Supreme Court, U.S.
FILED

991747 MAY 2 - 2000

No. _____

In The

Supreme Court of the United States

FRANK and LISA O'CONNELL, as legal representatives of their daughter, Kelli-Ann O'Connell,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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142pp

QUESTIONS PRESENTED

I. Whether § 300aa-14(c) of the National Childhood Vaccine Injury Act, which specifically authorizes the Secretary of Health and Human Services "to amend" a portion of the Vaccine Act, violates the Presentment and Bicameral provisions of Article I of the United States Constitution.

II. Whether § 300aa-14(c) impermissibly delegates legislative power to the Secretary of Health and Human Services.

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioners respectfully pray that a Writ of Certiorari be issued to review the decision of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit that gives rise to this Petition is unpublished but is based on the published decision in the companion case of *Terran v. Secretary of the Dep't of Health and Human Servs.* The Memorandum of Decision and Dissent are set forth in the Appendix as App. 1.5.

The opinion of the United States Court of Appeals for the Federal Circuit in the case of *Terran v. Secretary of Health and Human Servs.* is reported at 195 F.3d 1302 (Fed. Cir. 1999). The majority opinion in *Terran* and the dissent is set forth in the Appendix as App. 72-111. Petitioners understand that the *Terran* petitioners have or will file a Petition for a Writ of Certiorari as well.

JURISDICTION

The Court of Appeals for the Federal Circuit entered its judgment on November 1, 1999, App. 6. The Court of

Appeals denied a timely Petition for Rehearing on February 2, 2000, App. 45-46. Petitioners invoke the jurisdiction of this Court pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

Article I, § 7, cl. 2, provides in relevant part:

> Every Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it, with his Objections to that House in which it shall have originated, who shall enter the Objections at large on their Journal, and proceed to reconsider it.

Article I, § 7, cl. 3, provides:

> Every Order, Resolution, or Vote to which the Concurrence of the Senate and House of Representatives may be necessary (except on a question of Adjournment) shall be presented to the President of the United States; and before the Same shall take Effect, shall be approved by him, or being disapproved by him, shall be repassed by two thirds of the Senate and House of Representatives according to the Rules and Limitations prescribed in the Case of a Bill.

Article I, § 1, provides:

> All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

The case also involves the principle of separation of Powers, reflected throughout the Constitution.

Pertinent provisions of the National Childhood Vaccine Injury Act, Pub. L. No. 99-660, 100 Stat. 3755 (1986), partially codified at 42 U.S.C. § 300aa-1 *et seq.*, are reproduced at App. 47-60.

The Vaccine Injury Table and related provisions as amended by the Secretary, 42 C.F.R. § 100.3 (Oct. 1, 1996 ed.), are reproduced at App. 61-71.

STATEMENT OF THE CASE

In 1986, Congress wrote and passed and the President signed the National Childhood Vaccine Injury Act, Pub. L. 99-660, 100 Stat. 3755 (1986) (codified at 42 U.S.C. § 300aa-34) (hereinafter "the Vaccine Act"). The Vaccine Act limits the liability of vaccine manufacturers for injuries to children. In return, the Vaccine Act establishes a compensation system in the United States Court of Federal Claims before a Special Master.

The original Vaccine Act contained the Vaccine Injury Table at § 300aa-14(a). App. 47-60. The statutory Vaccine Injury Table is accompanied by the "Qualifications and Aids to Interpretation (QAI)." The statutory Vaccine Injury Table sets forth vaccines, medical conditions and time periods for first symptoms. Pursuant to 42 U.S.C. §§ 300aa-11, 13, if a child exhibits listed symptoms within a certain time period post-vaccination, then the vaccine is presumed to have caused the condition. The Administrator of the Program, the Secretary of Health and Human

Services ("the Secretary"), if she chooses to dispute the claim for compensation, has the burden to prove that the "table injury" was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. § 300aa-13(b). If an injured child does not have a "table injury" the child has the burden of proving "causation in fact."

Section 300aa-14(c) specifically allows the Secretary to "amend" and to "modify" the Statutory Vaccine Injury Table, and on March 10, 1995, the Secretary exercised that power. The administratively revised portion of the statute is now found at 42 C.F.R. § 100.3 (1986) and at App. 61-71. The regulatory amendments of the Table totally eliminated "Residual Seizure Disorder" from the list of Diphtheria, Postussis, Tetanus (DPT) table injuries and radically limited the definition of "Encephalopathy," practically eliminating it from the statutory table. *See* 42 C.F.R. § 100.3, App. 63-66.

The content of the Vaccine Injury Table is critical. If a child has a "table injury," she has a presumption of causation and most likely will recover compensation. If not, the child is left to prove "causation in fact" and is quite unlikely to recover. The importance of the burden of proof is illustrated by the General Accounting Office's ("GAO") recent report "Vaccine Injury Compensation, Program Challenged to Settle Claims Quickly," December 1999. The GAO found that petitioners forced to plead "causation in fact" were compensated at a dramatically lower rate than those claiming a "table injury." The GAO also found that 45% of the claims which had been awarded compensation were for injuries which the Secretary subsequently removed from the Table via amendment (pg. 14). Subsequently, the Vaccine Injury

Compensation Trust Fund, established by Congress to compensate injured children, has grown to $11.3 billion. The Trust Fund has lent $948 million of that total to the Treasury for other nonvaccine related uses. *Id.* pgs. 3, 16.

Pursuant to 42 U.S.C. § 300aa-12, the United States Court of Federal Claims has exclusive jurisdiction to determine if a child is entitled to statutory compensation. Section 12(f) of the Vaccine Act establishes exclusive appellate jurisdiction in the Federal Circuit.

On February 9, 1993, Kelli-Ann O'Connell received the DPT vaccine. On February 10, 1993, Kelli-Ann exhibited the first symptoms of a devastating and undeniable (by medical, if not statutory terms) Residual Seizure Disorder and Encephalopathy.

On February 5, 1996, the petitioners filed a petition for compensation. In light of the regulatory amendments to the statute, Petitioners alleged that the DPT vaccine had "in fact" caused Kelli-Ann's condition, which was no longer a "table injury." Under the original statutory table, Kelli-Ann satisfied the criteria for both "Residual Seizure Disorder" and "Encephalopathy" as "table injuries" and in all probability would have recovered compensation for her severe, intractable seizure disorder.

On February 2, 1998, after a full hearing on the merits in accordance with the March 10, 1995 regulatory amendments to the statutory Vaccine Injury Table, the Special Master found that Petitioners did not sustain their burden of causation in fact. App. 7-33. The United States Court of Federal Claims affirmed the Special Master's decision on May 13, 1998. App. 34-42.

Petitioners filed a timely appeal in the United States Court of Appeals for the Federal Circuit. On November 1, 1999, a divided panel of the Court affirmed the judgment. App. 1-6. The panel of the Federal Circuit heard the cases of *O'Connell v. Secretary of the Dep't of Health and Human Servs.* and *Terran v. Secretary of the Dep't of Health and Human Servs.* together. The majority and the dissent analysis is set forth primarily in *Terran*, App. 72-111.

The majority in both *Terran* and *O'Connell* held that while the Vaccine Act specifically allows for the Secretary to "amend" and "modify" the statutory Vaccine Injury Table, the Vaccine Act still does not violate the Presentment Clause or delegate legislative power to the Secretary.

Judge Plager filed a dissent in each case, citing this Court's decision in *Clinton v. City of New York*, 524 U.S. 417 (1998) in arguing that the clear and unambiguous language of the Vaccine Act, together with the legal and practical effect of the Secretary's regulations, illustrates that the Vaccine Act allows the Secretary to amend a statute in violation of the requirements of Article I. App. 100-111.

REASONS FOR GRANTING THE WRIT

The decision below clearly conflicts with this Court's decisions in *Clinton* and *I.N.S. v. Chadha*, 462 U.S. 919 (1982). In *Clinton*, this Court held unequivocally that: "There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes." 524 U.S. at 438. Moreover, the Court reaffirmed that:

" 'Amendment and repeal of statutes, no less than enactment, must confirm with Article I.' " *Id., quoting Chadha,* 462 U.S. at 954.[1] Despite this Court's unambiguous teaching, the decision below upheld a statutory scheme that expressly authorizes the Secretary "to amend" and "modify" statutory text. In dissent, Judge Plager underscored the clear conflict between the decision below and this Court's precedents: "the Supreme Court as recently as last year made clear that the Presentment Clause requires that any modification to a statute must follow [the procedures of Art. I, § 7, cl. 2]." *Terran,* 195 F.3d at 1319, App. 106. This clear conflict between the decision below and *Clinton* and *Chadha* justifies this Court's exercise of certiorari jurisdiction. *See* Supreme Court Rule 10(c).

In addition, the Federal Circuit's reasoning in avoiding the clear teaching of *Clinton* and *Chadha* provides an additional justification for granting certiorari. The Federal Circuit evaded *Clinton* and *Chadha* through misplaced reliance on this Court's non-delegation holding in *Field v. Clark,* 143 U.S. 649 (1892). Even though *Clinton* squarely rejected the government's reliance on *Field,* in the proceedings below the government beguiled the Federal Circuit into adopting its recycled argument. As elaborated below, this case clearly falls on the *Clinton* side of the dividing line between *Clinton* and *Field.* Accordingly,

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[1] *See also The Confiscation Cases,* 87 U.S. 92, 112-13 (1873) ("No power was ever vested in the President to repeal an act of Congress."); *City of New York v. Clinton,* 985 F. Supp. 168, 179 (D.D.C. 1998) ("Once a bill becomes a law, it can only be repealed or amended through another, independent legislative enactment, which itself must conform with the requirements of Article I."), *aff'd and quoted in Clinton,* 524 U.S. at 427 n.12.

the Federal Circuit's error demonstrates that the lower courts stand in need of further clarification of the *Clinton/Field* line. This case provides the Court with an excellent opportunity to amplify the distinctions between those cases or to clarify that *Field*'s holding is limited to the non-delegation doctrine, the theory raised and rejected in *Field*.

While there is no split of authority among the circuits as to the Vaccine Act's constitutionality, this is a function of the Federal Circuit's exclusive jurisdiction over Vaccine Act claims, not an indication that further percolation in the lower courts will sharpen the issues. Indeed, if the Court denies certiorari in this case and *Terran*, then those decisions likely will be the final word as to the constitutionality of this important federal statute, even though the decisions conflict with *Clinton* and *Chadha*.[2] This Court has not hesitated to grant certiorari on issues over which the Federal Circuit (or D.C. Circuit) has exclusive

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[2] While it is theoretically possible that another party could preserve this issue throughout the proceedings below and then file a petition for certiorari raising the issue, the unique compensation structure of the Vaccine Act makes such a course unlikely. The Act provides the exclusive mechanism for compensation of attorneys and places limits on which filings can result in compensation. *See* 42 U.S.C. § 300aa-15(e)(1) (court "may award" attorney's fees if it determines that "there was a reasonable basis for the claim for which the petition was brought"). If this Court rejects the petitions here and in *Terran*, it may be difficult for any subsequent attorney to justify litigating this issue in the lower courts and filing a petition for certiorari raising this issue. Accordingly, this may be the Court's best and last chance to consider this important issue and to correct the Federal Circuit's failure to follow *Clinton* and *Chadha*.

jurisdiction, when the case raises important constitutional or statutory issues. *See, e.g., Shalala v. Whitecotton*, 514 U.S. 268 (1995) (Vaccine Act case); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993) ("Because the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent cases, the rule it applied in this case . . . is a matter of special importance to the entire nation. We therefore granted certiorari."). It is hard to imagine issues of more surpassing importance than preserving the constitutional separation of powers and maintaining the integrity of the Presentment Clause.

Finally, the decision below rejected petitioners' non-delegation doctrine claim as well as their Presentment Clause argument. In *Clinton*, the three dissenting Justices viewed the case as raising non-delegation, rather than Presentment Clause, issues. The decision below considers both issues and provides the Court with an opportunity to elaborate on the proper mode of analysis. Moreover, as explained below, the explicit manner in which the Vaccine Act delegates the core Article I power to amend statutes may provide a basis for the dissenting Justices in *Clinton* to distinguish both *Field* and their opinions in *Clinton*.

I. SECTION 300aa-14(c) OF THE VACCINE ACT VIOLATES THE PRESENTMENT AND BICAMERAL REQUIREMENTS OF ARTICLE I OF THE UNITED STATES CONSTITUTION

In *Clinton v. City of New York*, 527 U.S. 417 (1998), this Court struck down the "Line Item Veto Act" because it

clearly and unambiguously allowed the President to "cancel" statutory provisions and to prevent portions of laws from having legal force and effect. 524 U.S. at 439. The President's actions "in both legal and practical effect" allowed the President unilaterally to amend the text of duly enacted statutes in violation of the strict Presentment and Bicameral provisions of Article I. *Id.* at 438. In *I.N.S. v. Chadha*, 462 U.S. 919 (1982), this Court struck down the legislative veto provision of the Immigration and Nationality Act, holding unequivocally that the power to enact statutes may only be exercised in accordance with a "single, finely wrought and exhaustively considered procedure", 462 U.S. at 951, and that "[a]mendment and repeal of Statutes, no less than enactment, must conform with Art. I". *Id.* at 944.

Despite the clear and unambiguous language of § 300aa-14(c) of the Vaccine Act, allowing the Secretary to "amend" the statutory table and despite the devastating legal and practical effect the Secretary's amendment of the statute had on Kelli-Ann O'Connell and all similarly situated children, the majority below held that the Vaccine Act does not violate the Constitution's strict Presentment and Bicameral Requirements, App. 88-93, and does not allow an unlawful delegation of power to the Secretary. App. 94-96. In dissent, Judge Plager classified the majority's finding that the Vaccine Act does not truly allow for "amendment" as "verbal obfuscation". App. 107. However, the majority committed a more egregious error than violence to the English language. The Federal Circuit's decision is in direct conflict with this Court's rulings in *Clinton* and *Chadha* on a matter of extreme constitutional importance, the separation of powers.

In addition to the gravity of the constitutional issue and the clarity of the conflict with this Court's precedent, there are other compelling reasons for granting certiorari. First, as the Court of Appeals for the Federal Circuit has exclusive jurisdiction over cases arising out of the Vaccine Act, no other circuit will have an opportunity even to point out the Federal Circuit's mistake, and only this Court can correct the mistake. Corresponding with the Federal Circuit's exclusive jurisdiction is the devastating practical effect of the Secretary's razing of the statutory table. Kelli-Ann O'Connell and all other children who exhibit certain original statutory "table injuries" are no longer entitled to compensation.

A. By Its Clear and Unambiguous Language § 300aa-14(c) Allows The Secretary "To Amend" A Statute

Despite the government's protestations that the Line Item Veto Act allowed statutorily cancelled items to have "real, legal budgetary effect," and therefore did not effectuate "amendments," this Court ruled in *Clinton* that the President's actions made statutory provisions "entirely inoperative as to Appellees," 524 U.S. at 441. While the Line Item Veto Act at least somewhat euphemistically allowed the President to "cancel" a statutory item and prevent it from having "legal force or effect," the Vaccine Act by comparison is brazen in its clear and specific authority to the Secretary to "amend" and "modify" the statutory Vaccine Injury Table. Courts are bound by a statute's plain, unambiguous language and cannot alter the terms and thus enact, instead of construe, the law.

Metropolitan and Stevedore Co. v. Rambo, 515 U.S. 291, 295 (1995); *Rake v. Wade*, 508 U.S. 464, 471 (1993).

Moreover, this is not a case where a separation of powers violation produces only indirect effects on institutional interests. *Cf. Raines v. Byrd*, 521 U.S. 811 (1997). Here, the failure to respect the separation of powers had a devastating effect upon Kelli-Ann O'Connell's rights. Clearly, the original statute allowed Kelli-Ann O'Connell and similarly situated children a right to an evidentiary presumption of causation. The Secretary destroyed those rights, making the statutory table "entirely inoperative as to (Petitioners)." *Clinton*, 524 U.S. at 441. The Federal Circuit's decision adopts the government's argument, supported by no authority whatsoever, that the Vaccine Act does not "really" allow for amendment, but simply creation of "new" tables. That ruling ignores both the clear language of the Vaccine Act as well as the obvious "legal and practical effect" of the Secretary's amendments.

B. The Vaccine Act Does Not Mandate Specific Executive Action

The Federal Circuit's misplaced reliance on *Field v. Clark*, 143 U.S. 649 (1892) provides another reason to grant certiorari. In *Clinton*, the government cited *Field* in arguing that the President's cancellations were not amendments, but merely exercises of discretionary authority. 524 U.S. at 442. While this Court dismissed that argument, the decision below adopted it entirely. The Federal Circuit was first incorrect in even analyzing the Vaccine Act pursuant to *Field v. Clark*. As this Court

clearly stated in *Clinton*, the Line Item Veto Act was constitutionally doomed by its own "unambiguous provisions." *Clinton*, 524 U.S. at 442. This Court considered *Field v. Clark* only in rejecting the same specious argument that the government made below and the Federal Circuit adopted in error in this case.

Even if *Field v. Clark*, which did not involve a Presentment Clause challenge, is relevant to the inquiry, an analysis of that case only further illustrates the Vaccine Act's infirmity. In *Field*, this Court upheld the constitutionality of the Tariff Act of 1890 which established a "free list" of articles that were exempted from import duties and also mandated the President to suspend that exemption for certain items whenever he found that any country imposed reciprocally unequal and unreasonable duties on the United States. In upholding the Tariff Act, this Court held that "nothing involving the expediency of the just operation of such legislation was left to the determination of the President . . . " *Field*, 143 U.S. at 693. Congress directed the President to specific action once he found specific facts and the President "had no discretion to the premises except in respect to the duration of the suspension." *Id.*

Even though the Line Item Veto Act specifically required the President to make detailed determinations that each cancellation would (1) reduce the federal budget deficit; (2) not impair any essential government function; and (3) not harm the national interest, this Court found that those determinations "do not qualify his discretion to cancel or not to cancel." *Clinton*, 524 U.S. at 443-44.

The Vaccine Act's proscriptions upon the Secretary are far less taxing than the three specific findings under the now constitutionally defunct Line Item Veto Act. As Judge Plager appropriately commented in dissent, App. 109, the Vaccine Act merely establishes committees and procedures requiring notice and comment on proposed amendments which do not bridle the Secretary's discretion in any meaningful way. Section 300aa-14(c) requires no mandatory action on the Secretary's part, nor does it require specific factual findings. Section 300aa-14(c)'s language is even discretionary in that the Secretary "may" (not "shall") promulgate regulations to modify the Table.

Section 312 of Pub L. 99-660, App. 56-60, directs the Secretary to perform "related studies" of vaccines and illnesses, but does not salvage the Vaccine Act. Section 312 speaks to a specific, single study and certain regulations the Secretary may propose. The Secretary's blanket, unilateral authority to amend under § 300aa-14(c) of the statute, however, is not limited to the studies and findings referenced in § 312.

Second, while § 312(a) requires the Secretary to conduct a study of eleven certain specific conditions, neither "Residual Seizure Disorder" nor "Encephalopathy" is among them. Section 312(a)(12), however, gives the Secretary carte blanche to review "such other illnesses and conditions that the Secretary may choose to review." Section 312(c) authorizes the Secretary "to amend" the Vaccine Injury Table "as a result" of the study.

Section 312 does not mandate specific action upon specific findings. The Secretary's only avenue to include "Residual Seizure Disorder" and "Encephalopathy" in a

study was her statutory authority to include whatever she "chooses to review." Congress did not even specify the subject matter of the study. Also, Section 312(c) provides no direction as to the methodology of the study, nor does it provide any direction as to how the Secretary is to make her decision to amend the statute "as a result of" the study.

The statute's paucity of restraint of the Secretary is best illustrated by the Secretary's actions "as a result of" her study of what she "chose to review." The Institute of Medicine study, pursuant to § 312, found that existing scientific evidence was inadequate to definitively reject or accept a causal relationship between vaccines and Residual Seizure Disorder. Nonetheless, the Secretary amended the Table by removing that condition. The same study, however, also found inadequate evidence to reject or accept a causal relationship between the measles and mumps vaccine and Encephalopathy, but the Secretary left that condition on the Table. Similarly, while the study favored acceptance of a relation between tetanus vaccine and brachial neuritis, the Secretary added that condition to the Table, but did not add Guilian Bar Syndrome to the polio vaccine table based on identical factual findings. "Gen. Acct. Off., Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily" (Dec. 1999) PG. 15. The lack of methodology and direction in § 312's "related study," allowed the Secretary to treat identical findings in the exact opposite way in amending the statutory table.

This Court upheld the Tariff Act in *Field v. Clark* because nothing involving the expediency or just operation of the legislation was left to the determination of the

President. 143 U.S. at 693. The Vaccine Act leaves everything to the Secretary, including the decision of whether or not to amend a statute with no constraints in § 14(c), save for the establishment of certain committees. Section 312 leaves the areas to be studied to the discretion of the Secretary as well as the treatment of the data. Congress abdicated so much to the Secretary that she could take the exact same conclusions of the study and then eliminate one injury from the Table and not the other. A *Field v. Clark* analysis in this case, while not necessary due to the Vaccine Act's "clear and unambiguous" language, further proves the Petitioners' point that the Vaccine Act unconditionally allows the Secretary to legislate.

C. The Secretary Has No Historical Discretion In The Administration Of Article I Courts

The Federal Circuit panel majority also ignored this Court's discussion in *Clinton* of the crucial difference between the President's actions under the Line Item Veto Act and the Tariff Act. Foreign trade is historically and traditionally within the executive's discretion. *Clinton*, 524 U.S. at 445. Even though the President clearly has historical spending powers, this Court found no historical and traditional justification for the Line Item Veto.

Similarly, this case involves no powers constitutionally or historically allocated to the executive. Indeed, the Vaccine Act addresses proceedings and evidentiary presumptions in an Article I court. In short, the Vaccine Act allows the Secretary a core Article I function (amendment) in a core Article I area (Article I courts). The Vaccine Act establishes a tribunal within the United

States Court of Federal Claims, an Article 1 court, for compensation for victims of vaccines. This Article 1 Court has exclusive jurisdiction over such claims, at least until the Court has entered final judgment. Injured children may then and only then pursue a more traditional tort recovery in state or federal court. The Vaccine Act even limits that conditional "traditional" tort recovery (trials are bifurcated and petitioners may only prevail in a subsequent action if they can prove that the injury was "unavoidable").

The Secretary's amendments totally reversed the burden of proof, making it much more difficult if not impossible for Kelli-Ann O'Connell and similarly situated children to recover. This Court has consistently held that Congress possesses the sole power of creating Article I courts and vesting them with jurisdiction. *Cary v. Curtis*, 44 U.S. 236, 245 (1845); *Palmore v. United States*, 411 U.S. 389, 401 (1973). By amending the statutory Injury Table, the Secretary radically altered the rights and obligations not only of litigants in an Article 1 court, but also by implication the jurisdiction of that Article 1 court. Special Master's hearings are bifurcated between entitlement and damages. As less injured children are entitled to a presumption of causation, less children will prevail on entitlement and the Article I Court of Federal Claims will have no jurisdiction over damages. Not only does the Secretary have no historical or traditional role in the administration of Article 1 courts, that power is solely vested in Congress.

II. SECTION 300aa-14(c) IS AN UNCONSTITUTIONAL DELEGATION OF LEGISLATIVE POWER

A. Section 300aa-14(c) Delegates An Essential Legislative Function to the Secretary

It is a bedrock principle of constitutional law, derived from Art. I, § 1's grant of "[a]ll legislative Powers" to Congress, that "the lawmaking function belongs to Congress . . . and may not be conveyed to another branch or entity." *Loving v. United States*, 517 U.S. 748, 758 (1996). Congress may delegate to the Executive Branch broad authority to make rules and to implement laws, but Congress may not delegate the core legislative power that Article I vests exclusively in it. *See, e.g., Field*, 143 U.S. at 692 ("That Congress cannot delegate legislative power to the president is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution.")[3] The Vaccine Act's express grant of the core Article I power of amendment to the Secretary violates this fundamental principle.

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[3] *Cf. Loving*, 517 U.S. at 776-77 (Scalia, J., concurring in part and concurring in the judgment) ("While it has become the practice in our opinions to refer to 'unconstitutional delegations of legislative authority' versus 'lawful delegations of legislative authority,' in fact the latter category does not exist. Legislative power is nondelegable. Congress can no more 'delegate' some of its Article I power to the Executive than it could 'delegate' some to one of its committees.").

Unsuccessful litigants have attacked congressional enactments as failing to provide an "intelligible principle" to guide an agency in its implementation of a statute. *See, e.g., Mistretta v. United States*, 488 U.S. 361, 372 (1989). The non-delegation problem in this case is distinct. The initial delegation question here is not whether the Vaccine Act fails to set forth an "intelligible principle" or allows the Secretary "too much" discretion in exercising the delegated authority. Rather, the question is whether the authority delegated is legislative power -- power that Article I, § 1, renders non-delegable.

By its own terms, and by its legal and practical effect, § 300aa-14(c) permits the Secretary "to amend" and "to modify" the provisions of a statute enacted by Congress and approved by the President. Amendment of statutes is a core, exclusive legislative power. *Clinton*, 524 U.S. at 438 ("There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes."); *Chadha*, 462 U.S. at 954 ("Amendment and repeal of statutes, no less than enactment, must conform with Art. I."). *See also City of New York v. Clinton*, 985 F. Supp. 168, 187 (D.D.C. 1998) ("it is irrelevant whether the Line Item Veto Act provides intelligible principles in its delegation of authority to the President because . . . the Act impermissibly attempts to transfer non-delegable legislative authority to the Executive Branch."), *aff'd on other grounds*, 524 U.S. 417 (1998).

The Secretary's amendment of the Table presents an important question even under the approach espoused by the *Clinton* dissenters. Justice Scalia, joined by Justice O'Connor and Justice Breyer, disagreed that the Presentment Clause "categorically prohibit[ed]" the cancellations

at issue. *See* 524 U.S. at 464-65. Justice Scalia instead viewed the cancellations as examples of "Executive reduction of congressional dispositions in the course of implementing statutes that authorize such reduction," *id.* at 464, and argued that such "authorized Executive reduction," *id.* at 465, should be analyzed under the nondelegation doctrine rather than the Presentment Clause. *See id.*, at 465 ("When authorized Executive reduction or augmentation is allowed to go too far, it usurps the nondelegable function of Congress and violates the separation of powers."). The dissenters, however, acknowledged that the limits on "Executive reduction" of statutes "may be much more severe" than the limits on "Executive augmentation" of statutes (a practice "generally known as substantive rulemaking"). *Id.* at 464-65.

This case involves a significant "reduction" by the Secretary of the statute enacted by Congress and signed by the President. The Vaccine Injury Act Table enacted as part of the statute provided presumptive compensation for a child who, like petitioner Kelli-Ann O'Connell, suffered from "Residual seizure disorder" and "Encephalopathy" following a DPT vaccination. *See* 42 U.S.C. § 300-aa-14(a)(I)(B)&(D), App. 47-50 (statutory Table); 42 U.S.C. § 300aa-14(b)(3)(A), App. 51-52 (statutory definition of "Encephalopathy"). The Secretary's amendment of that Table turned that presumption upside down, withholding compensation on the same facts unless the petitioners can carry the difficult burden of affirmatively proving causation in fact. *See* 42 C.F.R. § 100.3(a)(II), App. 63-64 (Table as amended by Secretary); 42 C.F.R. § 100.3(b)(2), App. 65, 66 (definition of "Encephalopathy" as amended by Secretary.)

Moreover, unlike the Tariff Act provisions at issue in *Field v. Clark*, the "Executive reduction" in this case was in no way "contingent upon an Executive finding of fact" specified by Congress in the initial enactment. *See Clinton*, 524 U.S. at 465 (Scalia, J., dissenting). Far from making the Secretary's amendment power contingent on a specified event or finding, the Vaccine Act simply provided that the Secretary "may" amend the Table. 42 U.S.C. § 300aa-14(c)(1). The Vaccine Act sets forth no standards whatever to control the Secretary's discretion in exercising her amendment power, leaving the Secretary free to rewrite Congress' handiwork as she sees fit. As this Court long has recognized, " '[t]he true distinction . . . is between the delegation of power to make the law, which necessarily involves a discretion as to what it shall be, and conferring authority or discretion as to its execution under and in pursuance of the law. The first cannot be done; to the latter no valid objection can be made.' " *Loving*, 517 U.S. at 758-59 (quoting *Field*, 143 U.S. at 693-94). In both form and effect, the limitless and standardless grant of amendment authority in this case is a "delegation of power to make the law." It therefore cannot be squared with Article I, § 1's vesting of "[a]ll legislative Powers" in Congress.

B. Section 300aa-14(c) Lacks an Intelligible Principle

Even if this Court finds that the delegation to the Secretary to literally amend a statute did not involve a core legislative power, the Vaccine Act still fails as it does

not set forth a sufficient "intelligible principle" to constrain the Secretary's actions, especially in light of the greater direction for "executive reduction" of statutory text. *See supra* 19-20.

Assuming the function is delegable in the first place, in order to make a lawful delegation, Congress must lay down by legislative act an "intelligible principle" by which the person or body authorized to exercise the delegated authority is directed to conform. *J.W. Hampton, Jr. and Company v. United States*, 276 U.S. 394, 406 (1928). In order for there to be an "intelligible principle," Congress must declare a policy with respect to the subject; Congress must set up a standard for the delegatees' actions which meaningfully bridles discretion, and Congress must require a finding by the delegatee. *Panama Refining Co. v. Ryan*, 293 U.S. 388, 415 (1935); *Mistretta v. United States*, 488 U.S. 361, 373 (1988).

In *Schecter Corp. v. United States*, 295 U.S. 495 (1935), this Court ruled that a portion of the National Industrial Recovery Act, which authorized the President to approve "codes of fair competition," was unconstitutional. Although the statute required the President to make specific findings regarding the trade groups proposing the codes, this Court found that Congress had not sufficiently established "the standards of legal obligation thus performing its essential legislative function." *Id.* at 530.

Similarly, in *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), the Court struck down Section 9C of Title I of the National Industrial Recovery Act, which authorized the President to prohibit the transportation of petroleum products. This Court held that the statute did not set

forth any criteria to direct the President when or under what circumstances to act, thereby allowing the President "unlimited authority to determine the policy and to lay down the prohibition or not to lay it down as he may see fit." *Id.* at 415.

Since *Schecter* and *Panama*, Congress has generally followed this Court's constitutional directive in delegating authority. For example, in *Touby v. United States*, this Court upheld the Controlled Substances Act which allowed the Attorney General to add certain controlled substances to schedules. 500 U.S. 160 (1991). This Court explained the necessity of speed in keeping pace with technological developments which enabled drug suppliers to create different "designer drugs." The "imminent hazard to public safety" standard, together with specific factors which the Attorney General needed to consider, created an intelligible principle. *Touby* also involved an executive augmentation, authorizing the addition of certain controlled substances to a schedule. The limits on the dramatic "executive reduction" in this case, the Secretary removing conditions from the statute's coverage, requires more severe limits. *Clinton*, 524 U.S. at 464-65. (Scalia, J. dissenting.)

Mistretta v. United States, 488 U.S. 361 (1989) offers an instructive comparison with this case. In constitutionally delegating sentencing guidelines to a special commission, Congress charged the commission with three specific goals, further specified four purposes, prescribed a specific tool for use in creating sentencing regulations, directed the commission with a specific tool to develop a system of sentencing ranges, set forth seven factors to guide the commission in formulating offense categories,

set forth eleven factors to the commission to consider in establishing defenses and set forth eleven characteristics for the commission to consider in establishing categories of defendants. *Id.* at 377.

While the imminent threat to public health requires swift action to keep up with potential controlled substance violations, the 1986 Statutory Vaccine Injury Table did not require such swift action. The delegation was not justified by "the inherent necessity of the government's coordination." *J.W. Hampton, Jr. and Company*, 276 U.S. at 406. In fact, it took the Secretary nine years to amend the Table. Congress, once it wrote and enacted the statutory table, had both the exclusive power and the practical ability to amend or repeal it.

The Vaccine Act, in contrast, merely provides that the Secretary "may" amend the statute. 42 U.S.C. § 300aa-14(c). This delegation provides *no* principle, let alone an "intelligible" principle, to guide and constrain the Secretary's discretion in deciding whether, when, how, or why to amend the statute. The Act simply establishes committees, but these do nothing to cabin the Secretary's discretion. This standardless grant of plenary amendment authority impermissibly delegates the "power to make the law." *See Loving*, 517 U.S. at 759.

Moreover, as even the dissenters in *Clinton* recognized, the Constitution requires greater limits on delegations that permit "Executive reduction" of statutes than those that permit "Executive augmentation" or substantive rulemaking. *See* 524 U.S. at 464-65 (Scalia, J., dissenting). The lack of any standards or limits in the delegation here left the Secretary to her own devices to remove

conditions from the Vaccine Act's coverage and thereby dramatically "reduce" an Act of Congress.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that this Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit be granted.

Respectfully Submitted,

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NOTE: Pursuant to Fed. Civ., R. 47.6, this disposition is not citable as precedent. It is a public record. The disposition will appear in tables published periodically.

United States Court of Appeals for the Federal Circuit

98-5134

FRANK and LISA O'CONNELL,
as legal representatives of their daughter,
Kelli-Ann O'Connell,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

DECIDED: November 1, 1999

Before PLAGER, LOURIE and CLEVENGER, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* CLEVENGER. Dissenting Opinion filed by *Circuit Judge* PLAGER.

CLEVENGER, *Circuit Judge*.

Frank and Lisa O'Connell ("the O'Connells") appeal from the decision of the United States Court of Federal Claims affirming the Special Master's denial of the O'Connells' petition for compensation under the National Child Vaccine Injury Act of 1986 (the "Vaccine Act"). *See O'Connell v. Secretary oF Health & Human Servs.*, No. 96-63V (Fed. Cl. May 13, 1998). We affirm.

I

On February 5, 1996, the O'Connells petitioned for compensation under the Vaccine Act for two injuries, residual seizure disorder ("RSD") and encephalopathy, allegedly sustained by Kelli-Ann O'Connell as a result of a diphtheria-pertussis-tetanus ("DPT") vaccination administered on February 9, 1991. Under the regulations in place at the time the O'Connells filed their petition, Kelli-Ann's conditions did not qualify for compensation under the Vaccine Injury Table. In particular, the Vaccine Injury Table that was applied to the O'Connells' petition became effective on March 10, 1995 (the "1995 Table"), and excludes RSD from the list of injuries associated with DPT vaccines. *See* 42 C.F.R. § 100.3 (1996). The 1995 Table, also narrowed the definition of an encephalopathy. Compare *id.* § 100.3(b)(2) (definition of encephalopathy under 1995 Table) with 42 U.S.C. § 300aa-14 ((b)(3)(A) (1994) (definition of encephalopathy at the time the Vaccine Act was enacted). As a result, the O'Connells' petition sought to show that the DPT vaccination caused in fact Kelli-Ann's conditions. *See O'Connell v. Secretary of Health & Human Servs.*, No. 96-63V, slip op. at 2 & n.2 (Fed. Cl. (Special Master) Feb. 2, 1998).

The Special Master, after a review of the facts, concluded that the O'Connells had failed to prove causation in fact and dismissed the petition on the merits. *See id.* at 21, 24. On appeal to the Court of Federal Claims, the O'Connells first argued that the Special Master incorrectly applied the standard for causation in fact. This argument was rejected by the Court of Federal Claims. *See O'Connell*, No. 96-63V, slip op. at 4-5 (Fed. Cl. May 13, 1998). The O'Connells also argued that the Special Master

erred in declining to apply the Vaccine Injury Table as it existed before the changes effected in March 1995. In essence, the O'Connells sought a ruling that the changed Table is unconstitutional and therefore unenforceable, and that the O'Connells' petition should therefore be processed by the Special Master under the old Table.

The Court of Federal Claims rejected the O'Connells' argument, and they timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

II

In this court, the O'Connells do not argue that their petition could prevail under the 1995 Table applied by the Special Master. Instead, they renew their constitutional challenges to the 1995 Table, asserting that the creation of that Table violates the Presentment Clause of the Constitution, see Art. I, § 7, cl. 2, and additionally violates separation of powers principles.

In a companion case, *Terran v. Secretary of Health and Human Servs.*, No. 98-5161 (Fed. Cir. Oct. 27, 1999), we held that the section of the Vaccine Act authorizing the Secretary of Health and Human Services (the "Secretary") to promulgate the 1995 Table does not violate the Constitution, and therefore that the 1995 Table is in full force and effect. *See id.*, slip op. at 22. Because the O'Connells make no argument that their petition can prevail under the 1995 Table, we have no choice but to affirm the decision of the Court of Federal Claims that affirmed the dismissal of the O'Connells' petition by the Special Master.

The Government also contends that the O'Connells' claim here is barred by principles of *res judicata* based on an earlier decision by our sister court, the United States Court of Appeals for the First Circuit. *See O'Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996). In that case, the O'Connells challenged the validity of the 1995 Table on the ground that the Secretary's changes to the Vaccine Injury Table exceeded the authority granted to her by Congress, but did not raise a constitutional challenge to the 1995 Table. *See id.* at 173 & n.2, 175. Because the O'Connells' argument fails on the merits, *see Terran*, No. 98-5161, slip op. at 22, we need not, and do not, decide this issue.

COSTS

No costs.

PLAGER, Circuit Judge, dissenting.

The O'Connells challenge the 1995 Vaccine Injury Table on the same constitutional grounds as the Appellant in *Terran v. Secretary of Health and Human Servs.*, No. 98-5161 (Fed. Cir. Oct. 27, 1999). The majority affirms the Court of Federal Claims' decision, affirming the dismissal of the O'Connells' petition, based on the holding in Terran that the section of the Vaccine Act authorizing the Secretary of Health and Human Services ("Secretary") to promulgate regulations revising the Vaccine Injury Table does not violate the Constitution. As explained in my dissent in *Terran*, I would hold that the section of the

Vaccine Act authorizing the Secretary to amend the statutorily-enacted Vaccine Injury Table violates the Presentment Clause of the Constitution, and therefore that the Secretary's 1995 attempt to revise the Vaccine Injury Table is of no legal effect. Accordingly, I would vacate the judgment of the Court of Federal Claims, and remand the case to that court with instructions to analyze the O'Connells' claims under the legislatively-enacted table in 42 U.S.C. § 300aa-14(a), and to process their claims accordingly.[1] I respectfully dissent from the contrary conclusion reached by the majority.

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[1] On remand the Government would have opportunity to raise the res judicata issue which the majority declines to address.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF
JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 11/01/99

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing in banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

No costs were taxed in this appeal.

Exhibits and visual aids shall be promptly retrieved by the party that lodged them with this court.

JAN HORBALY
Clerk

cc: BRIAN A. O'CONNELL
CHARLES R. GROSS

O'CONNELL V HHS, 98-5134
CFC-96-VV-63

In the United States Court of Federal Claims

OFFICE OF THE SPECIAL MASTERS

February 2, 1998

FRANK and LISA O'CONNELL as legal representatives of their daughter, KELLI-ANN O'CONNELL, Petitioners, vs. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	No. 96-63V PUBLISHED

Brian A. O'Connell, Wellesley, MA, for petitioners.

Kate Adam Coleman, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

On February 5, 1996, Frank and Lisa O'Connell, on behalf of their daughter, Kelli-Ann O'Connell (hereinafter "Kelli-Ann"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[1]

[1] The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 *et seq.* (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

(hereinafter the "Vaccine Act" or the "Act"). Pursuant to 42 U.S.C. § 300aa-11 (c), petitioners have satisfied the requirements for a prima facie case by showing that: (1) they have not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, (2) the DPT vaccination was administered to Kelli-Ann in the United States and, (3) they have incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.

Petitioners allege a causation-in-fact seizure disorder and encephalopathy following DPT. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I).[2] Respondent denies that DPT caused in fact Kelli-Ann's onset of seizures, seizure disorder, or encephalopathy.

The court held a hearing in this case on July 24, 1997. Testifying for petitioners were Lisa O'Connell and Dr. Marcel Kinsbourne. Testifying for respondent was Dr. Gerald M. Fenichel.

FACTS

Kelli-Ann was born on October 10, 1992. Petition at p. 1. She received her first DPT vaccination on December 10,

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[2] Under a change in the regulations, effective March 10, 1995, residual seizure disorder is no longer considered a Table injury. *See* 42 C.F.R. § 100.1-100.3. In addition, the definition of encephalopathy as a Table injury changed in such a way that Kelli-Ann's symptomatology would not satisfy the new regulations. *Id.* Thus, since petitioners filed their petition after the effective date of the regulations, they proceeded under a theory of causation in fact with respect to both the seizure disorder and encephalopathy.

1992 when she was two months old. Med. recs. at Ex. 7, p. 1. She received her second DPT vaccination on February 9, 1993 when she was four months old. *Id.*

On February 10, 1993, Kelli-Ann visited her pediatrician, Dr. Rekha Bains, with a complaint of decreased appetite, and brief, involuntary shaking of her left arm and right leg, amounting to twelve to thirty twitches. Med. recs. at Ex. 7, p. 4.

Subsequent to this visit, she was taken to Lowell General Hospital with a similar complaint. Med. recs. at Ex. 1, p. 4. A history taken at the hospital reflects that Kelli-Ann had twitching of her arms and legs since approximately 12:30 p.m on February 10, 1993. Med. recs. at Ex. 1, p. 4. The history further noted that she experienced mild twitching in her left arm and right leg two to three times on the day before she received her DPT.[3] *Id.* There was no record of fever. *Id.* She fed well in the morning of February 10, 1993; however, she was irritable and did not eat well since noon. *Id.* She experienced involuntary shaking, akin to tremors, which affected all four limbs, particularly her left arm and right leg. Med. recs. at Ex. 1, p. 4. On the way home from her visit with

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[3] In a signed statement obtained by respondent, dated July 23, 1997, Dr. Bains stated that this history is incorrect. "It is an error in dictation. There is no history of twitching or jerking before Kelli-Ann received her immunization for which she was seen in my office on 2/9/93. It should read – the child was given 1 dose of Tylenol and was keeping well through the night but the mother notes the baby to have mild twitching [in] left arm, right leg 2-3 times before being seen *TODAY.*" R. Ex. J (unpaginated). Dr. Bains also stated that Kelli-Ann was afebrile during her office visit on February 10, 1993. *Id.*

Dr. Bains, she again experienced jerking movements which were accompanied by mild movements of the jaw. *Id.* During these episodes, her eyes did not roll up nor did she have staring spells. *Id.* She did not vomit. *Id.*

A physical examination described Kelli-Ann as a playful, active child who appeared bright and alert. *Id.* She had normal tone and posture but was irritable. Med. recs. at Ex. 1, p. 4. She had mild nasal congestion, and her tympanic membranes were inflamed. *Id.* A nursing note reflects that she was alert, happy, and awake with a temperature of 100 degrees. Med. recs. at Ex. 1, p. 22.

A pediatric nursing assessment, recorded on February 10, 1993, stated that Kelli-Ann was alert, happy, and pale, with a good grasp and flat fontanelle. Med. recs. at Ex. 1, p. 20. At 6:00 p.m., she was playful, smiling, and fed well. Med. recs. at Ex. 1, p. 8. She was described as a well-looking baby. *Id.* However, at 7:30 p.m., Kelli-Ann was fussy and flushed, with a temperature of 101.4 degrees. Med. recs. at Ex. 1, p. 22. At 7:45 p.m., she experienced jerking of the right arm and leg, which lasted for two seconds. *Id.* She did not change color or have respiratory distress. Med. recs. at Ex. 1, p. 22. After this jerking episode, she started to fall asleep. *Id.* At 10:30 p.m., Kelli-Ann had jerking movements again. Med. recs. at Ex. 1, p. 8. Her temperature was 101.5 degrees, but she was still bright-eyed and playful. *Id.*

On February 11, 1993, Kelli-Ann's left arm was tremulous and she had a glassy look momentarily with pallor. Med. recs. at Ex. 1, p. 8. There was no jerking. *Id.* On examination, she was playful. *Id.* A sleep EEG was normal. Med. recs. at Ex. 1, p. 11. She was discharged home

with fever control to be performed with Tylenol and Amoxicillin for a possible urinary tract infection. Med. recs. at Ex. 1, p. 8. In view of a strong family history of febrile convulsions, she was to be put on Tylenol. *Id.*

Kelli-Ann returned to the Lowell General Hospital Emergency Room (ER) on February 13, 1993 with a diaper rash. Med. recs. at Ex. 1, p. 25. She had been on Amoxicillin for several days, and she had received intramuscular antibiotics earlier that week for a febrile seizure. *Id.*

On February 17, 1993, Kelli-Ann returned to the Lowell General Hospital ER with a complaint of a generalized seizure. Med. recs. at Ex. 1, p. 30. She had a minor seizure involving her right arm and right leg that morning. *Id.* She had had a temperature of 100.3 degrees and a decreased appetite. *Id.* In the past two days, she had been very cranky and her spitting up had increased. Med. recs. at Ex. 1, p. 30. She had been unwell since the prior week when she experienced tremors in her left arm and right leg. *Id.* The history given further noted that her cousin had been on Phenobarbital for seizures and she had a paternal grandfather with febrile seizures. *Id.* Although her urinalysis showed an increase in white blood cells, no abnormality was found when she was examined in the office. *Id.*

While in the ER, Kelli-Ann had a generalized tonic-clonic convulsion during which her eyes rolled up and her pupils dilated. *Id.* Her temperature was 100.5 degrees and her vital signs were stable. *Id.* She had a whitish nasal discharge and noisy respiration. *Id.* Her seizure stopped spontaneously. *Id.* The doctor's impression was a prolonged generalized seizure lasting one hour and ten

minutes. *Id.* It was noted that Kelli-Ann's mother had had two generalized seizures of unknown etiology. Med. recs. at Ex. 1, p. 34.

On February 17, 1993, Kelli-Ann was also taken to Massachusetts General Hospital. Med. recs. at Ex. 3, p. 1. The medical records indicate that Kelli-Ann was easily aroused from sleep and had good tone. Med. recs. at Ex. 3, p. 7. She had had explosive diarrheal stools six or seven times. Med. recs. at Ex. 3, p. 20. The impression was that her seizures were probably related to uremia.[4] *Id.* The history given by Mrs. O'Connell reveals that she had had two seizures in her teens. Med. recs. at Ex. 3, p. 4. In addition, Kelli-Ann's first cousin was treated with Phenobarbital for febrile seizures while her paternal grandfather had a seizure disorder during childhood. *Id.* A maternal grandmother had a benign brain tumor. *Id.*

On February 28, 1993, Kelli-Ann returned to the Lowell General Hospital ER with a complaint of approximately ten brief, two, three, and twenty second seizures. Med. recs. at Ex. 1, p. 36. Upon admittance to the hospital, she was active, playful, smiling, afebrile, and moving all extremities. *Id.*

On March 4, 1993, she was taken to the Lowell General Hospital ER to have her Phenobarbital level checked. Med. recs. at Ex. 1, p. 40. She returned the next day due to tonsillitis. Med. recs. at Ex. 1, p. 43. On March 9, 1993,

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[4] Uremia is "an excess in the blood of urea, creatinine, and other nitrogenous end products of protein and amino acid metabolism. . . . " *Dorland's Illustrated Medical Dictionary* 1790 (27th ed. 1988).

she returned because of a seizure. Med. recs. at Ex. 1, p. 45. However, she was without distress, appeared well, and smiled during this visit. *Id.*

From March 10 to 11, 1993, Kelli-Ann was in Lowell General Hospital because of seizure activity. Med. recs. at Ex. 1, p. 50. Upon admittance, her fontanelle was flat, her color pink, and she was alert, happy, and smiling. Med. recs. at Ex. 1, p. 64. The history given reflects that she had an increase in seizure activity on May 9, 1993. Med. recs. at Ex. 1, p. 53. She was also agitated and irritable. *Id.* Her seizures consisted of a sudden jerking of her arms and legs as well as a sudden darting of her eyes. *Id.* She remained awake through these episodes. *Id.* Before the seizures began, she would become irritable, and jerk and arch her back. *Id.* The medical records describe her as afebrile, alert, hyperactive, and babbling loudly. *Id.* She had increased flailing of her arms. Med. recs. at Ex. 1, p. 55. Five days prior to this hospitalization, she was seen in the office because of a mild fever, and ulcerative pharyngitis. *Id.* A throat culture showed streptococcus pneumonia. *Id.* Two EEGs were normal. *Id.* A family history of febrile seizures in a first cousin was again given. *Id.*

On March 24, 1993, Kelli-Ann returned to Lowell General Hospital for seizures. Med. recs. at Ex. 1, p. 71. She went back five days later to have her Depakote level checked. Med. recs. at Ex. 1, p. 77. She returned on April 1, 7, 23 and May 2, 1993 for seizures. Med. recs. at Ex. 1, pp. 80, 83, 86, & 91.

On May 6, 1993, she saw Dr. Elizabeth C. Dooling, a pediatric neurologist at Massachusetts General Hospital,

who diagnosed benign myoclonic seizures of infancy. Med. recs. at Ex. 5, p. 3.

On August 2, 1993, Kelli-Ann saw Dr. James J. Riviello, Jr., a neurologist with the Childhood Epilepsy Program at Children's Hospital. Med. recs. at Ex. 2, p. 75. The history given to Dr. Riviello reflects that Kelli-Ann had her first seizure the day after receiving her DPT. *Id.* This seizure was accompanied by a slight temperature of 100-101 degrees. *Id.* She experienced several other generalized seizures throughout the next twenty-four hours. *Id.* She had a normal EEG, and a normal head ultrasound. *Id.* One week later, she had a ninety-minute generalized, tonic-clonic seizure with a 100.5 degree fever. *Id.* Although she did not experience alteration of awareness during this seizure, she did get quiet after the event. Med. recs. at Ex. 2, p. 76. There has not been any regression in her intellectual or motor milestones with the exception of a slight regression when she began taking Phenobarbital. *Id.* On physical examination, she had a sloping forehead, protruding left ear, and hypertelorism.[5] Med. recs. at Ex. 2, p. 77. On neurological examination, she was alert, responsive, and social. *Id.*

On August 6, 1993, Kelli-Ann went to the Clinical Neurophysiology Lab to have her median nerve somatosensory evoked potential tested. Med. recs. at Ex. 2, p. 106. She had dysfunction in the cortical portion of the median nerve somatosensory pathway bilaterally. *Id.* On August 10, 1993, Kelli-Ann underwent an MRI, which

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[5] Hypertelorism is an "abnormally increased distance between two organs or parts." *Id.* at 799.

showed that her left temporal lobe appeared smaller than her right, and her myelinization[6] was borderline normal. Med. recs. at Ex. 2, p. 85.

On August 11, 1993, Kelli-Ann saw Drs. Uri Kramer and Gregory Holmes, who noted that the ninety-minute seizure was the only one that she had during which she was unconscious. Med. recs. at Ex. 2, p. 107. Two EEGs revealed right posterior slowing. Med. recs. at Ex. 2, pp. 107-08. Her development was normal. Med. recs. at Ex. 2, p. 109. Drs. Kramer and Holmes diagnosed Kelli-Ann as having benign myoclonic epilepsy of infancy. Med. recs. at Ex. 2, pp. 108-09.

From November 18-23, 1993, Kelli-Ann was at Children's Hospital due to increasing seizures. Med. recs. at Ex. 2, p. 138. Dr. Riviello wrote that she had a normal level of alertness. Med. recs. at Ex. 2, p. 139. He believed that she still had benign myoclonic epilepsy of infancy. Med. recs. at Ex. 2, p. 140. Although Mrs. O'Connell questioned whether there was a regression in speech, Dr. Riviello noted that Kelli-Ann continued to gain motor milestones and her physical exam revealed an alert, responsive and social child. Med. recs. at Ex. 2, p. 277.

On April 15, 1994, Kelli-Ann saw Dr. Mark Korson at Children's Hospital metabolism service. Med. recs. at Ex. 7, p. 79. In a letter dated April 18, 1994, he opined that she had a possible metabolic disorder, suggesting that

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[6] Myelin is "the substance of the cell membrane of Schwann's cells that coils to form the myelin sheath. . . . ; it has a high proportion of lipid to protein and serves as an electrical insulator. . . . " *Id.* at 1086.

testing be conducted to determine whether such was mitochondrial. Med. recs. at Ex. 7, pp. 79, 83.

On July 13, 1994, Kelli-Ann saw Dr. Frederick Andermann, a pediatric neurologist at McGill University, who noted that it was difficult to be certain whether Kelli-Ann's condition was related to DPT. Med. recs. at Ex. 4, p. 2. He diagnosed myoclonic epilepsy. Med. recs. at Ex. 4, p. 1.

TESTIMONY

Mrs. Lisa O'Connell testified first for petitioners. Kelli-Ann received her first DPT vaccination on December 10, 1992. Tr. at 10. She did not experience any problems after the vaccination; however, in December 1992, she did suffer from an ear infection, which was accompanied by a 100 degree fever.[7] Tr. at 9-10.

Kelli-Ann received her second DPT at approximately noon on February 9, 1993. Tr. at 10. On February 10, 1993, between 10:00 a.m. and 11:00 a.m., her arm jerked. Tr. at 10-11. At approximately 12:30 p.m., this jerking recurred; however, this time it included both arms and legs. Tr. at 11. These jerking motions lasted from seconds to over one-half hour. *Id.* During the half-hour seizure, Mrs. O'Connell could not rouse Kelli-Ann. Tr. at 13. She seemed asleep. *Id.* Subsequent seizures occurred at 4:00 p.m. and 8:00 p.m. Tr. at 11-12. During the 8:00 p.m. seizure, which was the last episode of that day, Kelli-Ann

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[7] Mrs. O'Connell testified that the fever was over 100 degrees; however, she further admitted that she, herself, did not take her daughter's temperature.

had a fever of 101 degrees. Tr. at 11-12, 15. Mrs. O'Connell did not, however, remember if Kelli-Ann was warm during the earlier episodes. Tr. at 15-16. Her whole body jerked that night. Tr. at 17. Kelli-Ann never received her third DPT. Tr. at 19.

Mrs. O'Connell further testified that there was a family history of seizure activity. Tr. at 19-21. Kelli-Ann's cousin had had a febrile seizure while Mrs. O'Connell, herself, had two grand mal, afebrile seizures while in high school, which caused her to be on Dilantin for one week. *Id.* In addition, a maternal second cousin had seizures as a child and a paternal cousin suffered from febrile seizures. Tr. at 20. Kelli-Ann's paternal grandfather also had seizures as a child. *Id.*

On February 17, 1993, Kelli-Ann had numerous brief seizures. Tr. at 21. She had one ninety minute seizure during which she was unconscious. Tr. at 22-23. In early March 1993, seizures became a daily event, with the majority taking the form of myoclonic jerks. Tr. at 26. Kelli-Ann's development seemed fine for a year after her seizures began. Tr. at 31. However, between January and February 1994, Kelli-Ann's seizures increased and she experienced real regression. *Id.* She regains the skills that she loses but continues to progress very slowly. *Id.* Although she first walked at three years of age, she cannot presently climb stairs or run. Tr. at 32-33. Her language skills improved after her first Early Intervention at eight months. Tr. at 32. However, rather than using sentences, she babbles. Tr. at 32-33. She is not toilet-trained. Tr. at 34. She attends preschool and is a very social and happy child. *Id.*

Although Kelli-Ann has experienced both afebrile and febrile seizures, she has not had infantile spasms. *Id.* She has also had seizures where her head drops and she bends at the waist. Tr. at 33. No etiology for her seizures has ever been given. Tr. at 38.

Dr. Marcel Kinsbourne, a pediatric neurologist, testified next for petitioners. He diagnosed Kelli-Ann as having a severe myoclonic seizure disorder, a degree of developmental delay, and encephalopathy. Tr. at 63. These conditions were caused in fact by her second DPT. *Id.* The onset of her encephalopathy occurred on February 10, 1993 and was reflected by the extended, repeated seizures that she experienced. *Id.* Thus, for Dr. Kinsbourne, the onset of seizures was the same time as the onset of encephalopathy. Tr. at 63-64, 66.

Dr. Kinsbourne stated that Kelli-Ann had three generalized seizures in twenty-four hours. Tr. at 64. During generalized seizures, patients are always unconscious. *Id.* He further opined that Kelli-Ann had status epilepticus within twenty-four hours of her DPT. Tr. at 68. Dr. Kinsbourne defined status epilepticus as either a seizure which lasts for more than one-half hour or multiple, repeated seizure episodes which occur over brief periods of time. *Id.*

The basis of his opinion rested on the fact that Kelli-Ann was a totally normal child who was in an ominous seizure state within twenty-four hours of receiving DPT. Tr. at 69. This toxic occurrence caused Kelli-Ann to become a totally different child from what she was prior to the DPT. *Id.*

Dr. Kinsbourne testified that it is normally conceded that DPT can cause generalized convulsions, and an acute encephalopathy. Tr. at 70-71. The fact that DPT can cause these conditions, thus, implies that a mechanism is at work. Tr. at 71. According to Dr. Kinsbourne, the National Childhood Encephalopathy Study (NCES)[8] discussed the biological plausibility of the causal link between DPT and seizures and encephalopathy. *Id.*

Dr. Kinsbourne favors a particular mechanism of causation. *Id.* Pertussis vaccine contains pertussis toxin (exotoxin) and endotoxin[9]. Tr. at 71-72. The pertussis toxin and the endotoxin are both absorbed into the blood stream after vaccination. Tr. at 73. The endotoxin can have multiple effects, such as an increase in the permeability of the small blood vessels[10] and, in rare cases, an increase in the

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[8] *See* Alderslade, R., *et al.*, "The National Childhood Encephalopathy Study, Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunisation," 79-184 (London 1981).

> [T]he relative rarity of acute encephalopathic disorders in children, the diversity of potential aetiological agents, the large proportion of affected children in whom no cause for the illness can be established, and the similarity of the clinical features associated with different aetiologies, all conspire to create special difficulties in any attempt to demonstrate that pertussis vaccine rather than some other agent causes these conditions in some cases.

Id. at p. 96.

[9] All DPT vials contain different amounts of endotoxin. Tr. at 94.

[10] This effect has been shown in animal experimentation. Tr. at 73.

permeability of the blood-brain barrier. *Id.* Pertussis toxin also has potent effects on the functioning of neurons. Tr. at 74. The G proteins instruct the neurons in intercellular and intracellular functioning. *Id.* Pertussis toxin blocks the activity of the G proteins. *Id.* As such, the neurons either fire in excess or not at all. *Id.* Inhibitory neurons stop functioning, leaving other neurons to function excessively. Tr. at 74-75.

Dr. Kinsbourne testified that only non-specific clinical symptoms, such as seizures or change in level of consciousness, manifest while these processes occur. Tr. at 75-76. By merely describing these symptoms, one could not deduce the cause of such symptoms from the symptoms themselves. Tr. at 76. Furthermore, these processes could occur without the presence of symptoms, like inconsolable screaming and fever. Tr. at 77. Dr. Kinsbourne does not emphasize screaming or fever in his diagnosis of the neurological effects of DPT because the vaccine, itself, is painful and hurts the child. *Id.* Oftentimes, the vaccine site is red and swollen. *Id.* As such, the common screaming which results due to this pain cannot be distinguished from the less common encephalopathic screaming. *Id.* The same reasoning applies to fever. *Id.* Since fever is a common reaction to vaccination, it, alone, does not indicate neurological damage. *Id.* Thus, Dr. Kinsbourne found the fact that Kelli-Ann was afebrile during her first seizure to be irrelevant. Tr. at 69-70.

Seizure disorders in infancy have many causes, one of which is DPT. Tr. at 118. Dr. Kinsbourne diagnosed Kelli-Ann as having severe myoclonic epilepsy, opining that her seizure disorder began explosively with multiple

seizures, and myoclonus.[11] Tr. at 78, 83-84. He has not, however, seen any progression of encephalopathy in Kelli-Ann. Tr. at 119. Although the mechanism of damage from seizures is unknown, they are regularly associated with flattening out of development. Tr. at 82. Kelli-Ann took one year to show substantial developmental delay. Tr. at 81-82. While the rate at which she acquired skills was flattened, it was also punctuated with actual, temporary loss of skills when her seizures increased. Tr. at 82. A lot of seizure activity disturbs computation of the brain while anti-convulsants depress mental function. *Id.* The large amount of seizure activity as well as the use of anti-convulsants can explain Kelli-Ann's loss and retention of skills; however, Dr. Kinsbourne stated that her developmental delay is due primarily to her seizures. Tr. at 82-83.

Dr. Kinsbourne thought that Kelli-Ann's family history of seizures was irrelevant. Tr. at 86. The family's history of grand mal seizures is different than the type of seizures she experiences. *Id.* Kelli-Ann's seizures are predominantly myoclonic. *Id.* Dr. Kinsbourne also found fever to be irrelevant in Kelli-Ann's case because she did not present with convulsions.[12] Tr. at 86-87. Rather, she presented with myoclonus, which is epilepsy with or without fever. *Id.* She had an absolutely focal onset. Tr. at 89.

Dr. Kinsbourne noted that the fact that Kelli-Ann suffered status epilepticus the day after her DPT was

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[11] Myoclonus is a brief, shock-like contraction of the muscle groups. Tr. at 78.

[12] Dr. Kinsbourne noted that the only relevancy fever has is in relation to benign febrile convulsions.

significant in that it reflected the seriousness of her condition, and allowed her to meet the criteria of the NCES. Tr. at 95-96. He further testified that Kelli-Ann satisfies the NCES criteria because: (1) she had more than one seizure, (2) the seizure was longer than one-half hour and, (3) the seizures were focal. Tr. at 133. She had a spectrum of seizures in the first twenty-four hours which included jerks affecting one limb for a short period, jerks affecting limbs on the same side, jerks affecting opposite limbs, jerks affecting all four extremities, and an episode of glazed, staring eyes. Tr. at 134.

On cross-examination, Dr. Kinsbourne admitted that his basis for concluding that DPT caused Kelli-Ann's seizures and encephalopathy is not solely the breach of the blood-brain barrier. Tr. at 124. Dr. Kinsbourne testified that he did not know of any literature which discusses this theory. Tr. at 126. Although he is uncertain whether the blood-brain barrier theory is the mechanism which causes neurological events after vaccination, he stated that it is a biologically plausible theory. *Id.* However, there is no clinical way to determine if the blood-brain barrier is breached. Tr. at 131.

When challenged to find the one-half hour seizure in the records, Dr. Kinsbourne stated that it did not matter whether such seizure was generalized. Tr. at 136-38. He opined that having as many seizures over twenty-four hours as Kelli-Ann experienced constitutes status epilepticus, which is serious, neurological illness. Tr. at 139. He found no significance in the fact that Kelli-Ann's tympanic membranes were inflamed, stating that such diagnosis was subjective. Tr. at 141. He further noted that a child with a serious, acute neurological illness can still be

alert, and have a normal EEG. *Id.* Even if one is suffering from a toxic insult, which causes a neurological illness, the EEG can be normal depending on what part of the brain is damaged. Tr. at 141-42. Although exactly what portion of Kelli-Ann's brain is damaged is unknown, Dr. Kinsbourne testified that she experienced myoclonus, which arose from somewhere deep in her brain. Tr. at 142-43.

In Dr. Kinsbourne's opinion, timing is critical to his opinion on causation. Tr. at 146. Acute neurological damage from pertussis occurs within seventy-two hours. Tr. at 147. The largest number of reactions occurs within twenty-four hours of vaccination. *Id.* He admitted that there is no medical literature that associates DPT and myoclonic seizures. Tr. at 150.

Dr. Gerald Fenichel, a pediatric neurologist, testified for respondent. His opinion is that DPT did not cause Kelli-Ann's seizures. Tr. at 154. Rather, Kelli-Ann has progressive myoclonic epilepsy. Tr. at 156. Although she did not have a serious, acute encephalopathy the day after she received DPT, he does not know if she has a progressive encephalopathy.[13] Tr. at 154-55. Her seizure disorder progressed, during which time her seizures caused her brain to become worse. Tr. at 155.

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[13] Dr. Fenichel noted that Kelli-Ann does not have a progressive encephalopathy in the sense that she has a degenerative disease of the nervous system; however, she does have a progressive brain disorder. Tr. at 155.

The cause of most myoclonic encephalopathies as well as the mechanism for how DPT can produce encephalopathy is unknown. *Id.* at 156-58. Even without understanding the mechanism, Dr. Fenichel can accept causation when a child receives a DPT, develops a serious, acute neurological disorder within three days, and then is left with a chronic neurological disorder. Tr. at 158, 184. DPT can cause acute, serious neurological illness; however, not all acute, serious neurological illnesses are encephalopathy. Tr. at 188-89. Because Kelli-Ann was awake, alert, playful, and had a normal EEG, Dr. Fenichel found it incomprehensible for her to have had an acute, serious neurological disorder the day after the DPT vaccination. Tr. at 158-59. Moreover, she would not have been included in the NCES because she was discharged from the hospital the next day, and no one in the NCES was discharged after one day. Tr. at 159.

Dr. Fenichel defined "myoclonus" as a sudden, jerking movement that results: (1) from a seizure, (2) during sleep, or (3) from a movement disorder which is not a seizure. *Id.* Regardless of the cause, these jerks look the same. Tr. at 160. He defined status epilepticus as either twenty to thirty minutes of continuous seizure or repeated seizures that occur without recovery to normal function between each episode. Tr. at 165. The medical records are devoid of evidence that Kelli-Ann had status epilepticus. Tr. at 166. Dr. Fenichel noted that she could not have been awake when she reached the hospital if she had had twenty minutes of generalized tonic-clonic convulsions in the car. *Id.* Moreover, having multi-focal seizures while being bright and alert is inconsistent with status epilepticus. Tr. at 168. Finally, while most status

epilepticus has a known cause, Dr. Fenichel does not know the cause of Kelli-Ann's seizure disorder. Tr. at 161-63.

Dr. Fenichel testified that his opinion would not change regardless of the fact the Dr. Bains' record incorrectly stated that Kelli-Ann experienced twitching prior to her DPT.[14] Tr. at 172. Kelli-Ann had twitching or myoclonic seizures on February 10 and 11, 1993. Tr. at 173. The hospital did not diagnose her as having epilepsy at the time of admission. Tr. at 174-75. Her family has a genetic, underlying benign epilepsy which is temporary. Tr. at 175.

Dr. Fenichel admitted that Kelli-Ann has a seizure disorder. Tr. at 176. While he would not use the term encephalopathy to describe her condition, he admits that something is wrong with her brain. *Id.* DPT does not cause chronic encephalopathy; however, DPT may cause acute encephalopathy, followed by a chronic course. Tr. at 177. Although Kelli-Ann developed a very serious neurological illness, the onset did not occur on the same day as her seizures. Tr. at 178. She did not have a seizure lasting thirty minutes on the day following her DPT. *Id.* Rather, she had migrating multi-focal seizures which came and went during the twenty-four hours after her DPT. Tr. at 178-79. Dr. Fenichel noted that Kelli-Ann did not have a febrile seizure. Tr. at 181.

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[14] *See* R. Ex. J (unpaginated).

However, he has never seen migratory multi-focal, myoclonic seizures with fever and finds the presence of fever to be irrelevant to his opinion.[15] Tr. at 182, 193.

With regard to Mrs. O'Connell's recitation of the factual events involved in this case, Dr. Fenichel stated that most parents are disturbed when their children have seizures and their recollections are not always perfect. Tr. at 180. Records created closer in time to the incident are generally more accurate than those created later in time. Tr. at 180-81.

DISCUSSION

A. Encephalopathy

Petitioners allege that Kelli-Ann suffered an acute encephalopathy which was caused in fact by her DPT vaccination. To satisfy their burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." *See Grant v. Secretary, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Agarwsal v. Secretary, HHS*, 33 Fed. Cl. 482, 487 (1995); *see also Knudsen v. Secretary, HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). "[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." *Grant, supra*, 956 F.2d at 1149.

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[15] In addition, there is no significance in Kelli-Ann's nasal congestion or inflamed tympanic membrane. Tr. at 165.

Mrs. O'Connell testified that Kelli-Ann had a seizure which lasted for one-half hour on February 10, 1993 during which she was unconscious; however, this testimony is totally unsubstantiated by the multiple histories she gave to doctors on that day and during later visits. Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948); *Burns v. Secretary, HHS*, 3 F.3d 415 (Fed. Cir. 1993); *Ware v. Secretary, HHS*, 28 Fed. Cl. 716, 719 (1993); *Estate of Arrowood v. Secretary, HHS*, 28 Fed. Cl. 453 (1993); *Murphy v. Secretary, HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. denied sub nom. Murphy v. Sullivan*, 113 S. Ct. 263 (1992); *Montgomery Coca-Cola Bottling Co. v. United States*, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment. *Cucuras v. Secretary. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id.

A review of the histories that Mrs. O'Connell gave reflects the following. On February 10, 1993, the day the seizures began, Mrs. O'Connell told Dr. Bains that Kelli-

Ann had had twelve to thirty twitches, i.e., brief, involuntary shaking. Med. recs. at Ex. 7, p. 4. However, a medical record from Lowell General Hospital, also recorded on February 10, 1993, notes that Kelli-Ann experienced brief seizures. Med. recs. at Ex. 1, p. 4. One week later, the Lowell General Hospital ER Record reflects that Kelli-Ann had a one hour and ten minute seizure. Med. recs. at Ex. 1, p. 30. On August 2, 1993, Mrs. O'Connell told Dr. Riviello that Kelli-Ann had a ninety-minute seizure one week after her DPT. Med. recs. at Ex. 2, p. 75. On August 11, 1993, she told Drs. Kramer and Holmes that the ninety-minute seizure was the only seizure during which Kelli-Ann lost consciousness. Med. recs. at Ex. 2, p. 107.

While these histories describe a variety of events during the twenty-four hours after Kelli-Ann's DPT, there is no mention of the thirty-minute seizure about which Mrs. O'Connell testified. The court must conclude that Kelli-Ann did not suffer a seizure of thirty minutes or longer or lose consciousness during the twenty-four hours after her DPT. Accordingly, the court further finds that she did not have status epilepticus during this time. Based on these histories, the court does, however, conclude that Kelli-Ann experienced multiple, short jerks and twitches after her DPT.

Without an alteration in consciousness, Kelli-Ann's encephalopathy, as defined by Dr. Kinsbourne, means merely that her brain is abnormal. Otherwise, it is difficult to see why anyone would diagnose a smiling, alert, happy, playful, and responsive child as encephalopathic. But, it is unreasonable to believe that the doctors who treated Kelli-Ann somehow missed diagnosing her as having encephalopathy. They did not make this diagnosis

because she did not have encephalopathic symptoms. Dr. Kinsbourne's diagnosis of encephalopathy is unpersuasive to the court because it rests on events that the court finds did not occur (seizing for more than thirty minutes and losing consciousness within twenty-four hours of DPT) and extends the meaning of encephalopathy so generally (an abnormal brain) as to be meaningless.

The court does not accept Dr. Kinsbourne's thesis that anyone who seizes has an encephalopathy or, at least, an acute encephalopathy. Certainly, there would be ample medical justification for supposing that someone born with a chronic encephalopathy could begin seizing at any time. This, however, is not petitioners' allegation. Rather, they allege, *inter alia*, that Kelli-Ann had an acute encephalopathy one day after her DPT at the same time she began seizing.

Based on the foregoing, petitioners have not satisfied their burden of proving that Kelli-Ann had an acute encephalopathy within seventy-two hours of her receipt of DPT. Since seventy-two hours is the outer limit to which Dr. Kinsbourne will go in diagnosing a DPT-induced acute encephalopathy, petitioners have failed to satisfy their burden of proving that DPT caused Kelli-Ann to have encephalopathy.[16]

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[16] This does not mean that at some point during her seizure disorder, Kelli-Ann did not manifest symptoms of chronic encephalopathy.

B. Seizure Disorder

Petitioners have also alleged that Kelli-Ann's DPT vaccination was the cause in fact of her seizure disorder.

This court has previously held that DPT vaccine can cause a fever which in turn causes the onset of a seizure disorder. *McMurry v. Secretary, HHS*, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. July 27, 1997). In *McMurry*, petitioners similarly alleged a causation in fact seizure disorder.[17] *Id.* at * 1. In that case, the child had a high fever and seized for fifty or more minutes following her DPT. *Id.* at * 1-2. In addition, she was unresponsive and in status epilepticus. *Id.* Based on the occurrence of the fever as well as the onset of severe seizures, the court held for petitioners. *McMurry, supra*, at *8-9.

McMurry and this case are easily distinguished based on the vaccinees' symptomatology. In this case, Kelli-Ann did not have a fever during her initial seizures. Rather, she had a fever only after she had been brought to the hospital. Moreover, the court does not believe that she had status epilepticus during the twenty-four hours after her DPT. Her seizures were twitches and she never lost conciousness. Based on this lack of severity of symptoms, petitioners in the instant action clearly have a more difficult causation in fact case to prove than did the petitioners in *McMurry*.[18]

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[17] Unlike the instant action, petitioners in *McMurry* did not allege encephalopathy.

[18] The court recognizes that both medical experts herein thought that the presence or absence of fever was irrelevant to their opinions; however, both Drs. Kinsbourne and Fenichel

Dr. Kinsbourne posited a logical sequence of cause and effect, which relied partly on timing, and partly on a biologically plausible theory, i.e., the breaching of the blood-brain barrier.[19] While he opined that there would be no clinical symptoms of such an immunological affront to the system, the court has previously held that post-DPT symptoms of extreme irritability, anorexia, and insomnia, followed by lethargy and death, are evidence of a DPT toxic effect on a vaccinee. *Misenko v. Secretary*, HHS, No. 92-0013V, 1995 WL 761436, at *14-15 (Fed. Cl. Spec. Mstr. Dec. 7, 1995). However, Kelli-Ann did not experience any of these symptoms. Although the initial seizures eventually followed a path of intractability and developmental delay, a happy, functional, responsive, playful, and alert child is simply not experiencing a serious, acute neurological illness.

The court's recent Omnibus decision in *Barnes v. Secretary. HHS, et al.*, No. 92-0032V, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997), which essentially addresses respondent's burden of proof with respect to a factor unrelated defense in a significant aggravation context, is also helpful in analyzing whether petitioners herein have met their causation in fact burden. Petitioners in Barnes did not have the burden of proving that DPT caused their

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testified in *McMurry* that fever triggers seizures. Dr. Fenichel had no problem stating that the fever Rebecca McMurry had prompted her seizures, and the DPT caused her fever.

[19] This theory suggests that pertussis toxin and endotoxin, which are both present in DPT, breach the blood-brain barrier, permitting interference with the firing of neutrons [sic].

children's onset of seizures since these were Table injuries. *Id.* at * 33. Respondent had the burden of proving that a factor unrelated, tuberous sclerosis (TS), caused in fact petitioners' onset of afebrile seizures. Where there were no symptoms except the seizures themselves, and there was overwhelming proof that TS's common symptomatology was afebrile seizures, the court held that respondent met its burden of proof that a known factor unrelated (TS) caused the onset and that DPT did not significantly aggravate their TS. *Id.* at *34.

The instant action is analogous to the aforementioned cases because petitioners have the burden, post-1995 regulations, of proving that DPT caused Kelli-Ann's seizures. Thus, the fact that Kelli-Ann did not have any post-DPT symptoms, such as fever, anorexia, screaming, crying, insomnia, loss of affect, lethargy, unresponsiveness, etc., has some bearing on the causative relationship *vel non* of DPT and the onset of Kelli-Ann's seizures, particularly in light of the biologically plausible scenario that underlies Dr. Kinsbourne's opinion of causation. In the instant case, the only manifestation that Kelli-Ann had was twitching. Kelli-Ann was hospitalized for one day. No one diagnosed status epilepticus. The hospital would certainly have kept her longer if her medical condition warranted concern at that time. Her seizures appeared so mild that the initial diagnosis of even her pediatric neurologists was benign myoclonic epilepsy of infancy. The court must assume that the onset of the twitching was purely coincidental to the administration of DPT the previous day.

Petitioners have not satisfied their burden of proving that DPT caused Kelli-Ann's seizure disorder.

Respondent has pressed periodically for the court to hold that petitioners must precisely describe a causative mechanism in order to satisfy their burden of causation of fact. However, in *Knudsen v. Secretary HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994), the Federal Circuit stated that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." Moreover, herein, respondent's expert, Dr. Fenichel, admitted that DPT can cause serious, acute neurological illness, yet no one knows how. In *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (1994), the Institute of Medicine (IOM) noted, upon considering all of the pertinent medical literature available, that DPT can cause serious, acute neurological illness, which is followed by chronic nervous system dysfunction. *Id.* at 12. Yet, the IOM did not describe an exact mechanism underlying its conclusion. Respondent's demand for precise proof as to a causative mechanism is certainly not warranted either in law (*Knudsen*) or in medicine (IOM).

CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

DATE: Feb. 2, 1998

/s/ Laura D. Millman
Laura D. Millman
Special Master

In the United States Court of Federal Claims

No. 96-63 V

Filed: May 13, 1998

FRANK and LISA O'CONNELL as legal representatives of their daughter, KELLI-ANN O'CONNELL,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

ORDER

AFFIRMING SPECIAL MASTER'S DECISION

This case comes before the court on petitioners' motion for review of the decision of the special master, entered February 2, 1998, denying a claim to compensation under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified, as amended, at 42 U.S.C. §§ 300aa-1 to 300aa-34 (1994 & Supp. I 1995)) for neurological injuries – encephalopathy and residual seizure disorder – allegedly sustained by their daughter, Kelli-Ann, as the result of a diphtheria-pertussis-tetanus ("DPT") vaccine administered on February 9, 1991.

I

A

To prevail on their claim, petitioners were required to show, by a preponderance of the evidence, that the vaccine was the cause in fact of Kelli-Ann's impairments. They did not succeed. The special master's decision rejecting petitioners' claim starts with the proposition, acknowledged by both parties' experts, that a DPT-caused neurological injury is distinguished or identified by the occurrence of an acute encephalopathic event within the first seventy-two hours of the vaccine's administration. Petitioners' proof fell short of meeting this requirement on two basic grounds.

First, the special master declined to find, for lack of substantiation in the contemporaneous medical records, that, on the day following her receipt of the vaccine, Kelli-Ann experienced a seizure-related diminution of consciousness that lasted up to one-half hour. (The medically recognized significance of such an event, coupled with the absence of any noted reference to it in the medical histories that were prepared on and immediately after the day in question, persuaded the special master that the testimony describing such an event that was offered at the hearing, though honestly given, had been colored by the passage of time).

Second, the special master rejected the position asserted by petitioners' expert, Dr. Marcel Kinsbourne, that multiple, repeated seizure episodes occurring over a brief period of time, even though interspersed with returns to full alertness, could be regarded as status epilepticus, *i.e.*, a seizure condition lasting in excess of

one half hour. (The rejection was founded on the testimony of respondent's expert, Dr. Fenichel, who testified that "[j]ust having a seizure, recovering, and having another seizure is not status epilepticus. You have to have a series of seizures in which you have no recovery to normal function in between seizures.")

B

In their appeal to this court, petitioners raise two broadly related issues. First, they contend that the special master erred as a matter of law in adopting, as a requirement in the proof of a DPT-caused non-Table injury, evidence of the occurrence of a serious neurological illness, as demonstrated through a seizure-related period of reduced consciousness occurring within the first three days following immunization. That standard of proof, petitioners contend, simply mimics the more restrictive requirements now recognized in the Vaccine Act for the proof of a DPT-caused Table injury and thus, as a practical matter, precludes the availability of relief to all claimants whose DPT-related injuries are not initially manifested through an acute encephalopathy that is characterized by a prolonged reduction in consciousness.[1]

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[1] Pursuant to the Vaccine Injury Table, an encephalopathy occurring within 72 hours of the administration of the DPT vaccine is presumed to be a vaccine-caused illness or injury. 42 U.S.C. § 300aa-14(a) (1994 & Supp. I 1995), *amended by* 42 C.F.R § 100.3 (1997).

The "Qualification and aids to interpretation" that accompany the Vaccine Injury Table instruct that an encephalopathy within the meaning of the Table requires an injury, *i.e.*, an encephalopathy, having both acute (immediate)

Petitioners sum up their argument in these words: "In ruling on Kelli-Ann's theory, the Special Master (and the respondent's expert), applied the Table standard (and Table definitions) of 'acute encephalopathy' to analyze whether Kelli-Ann had proved her off Table theory. It was an error of law for the Special Master to have done so."

The other point that petitioners raise here concerns the revision to the Vaccine Injury Table that the Secretary of the Department of Health and Human Services introduced in 1995. Among the revisions then made by the Secretary were the elimination of residual seizure disorders from the list of DPT-related Table injuries and the introduction of a more restrictive definition for the identification of a Table-based encephalopathy. The contention put forward here is that neither of these changes can pass constitutional muster – and thus cannot be invoked against petitioners now – because the statutory authority under which they were accomplished – section

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and chronic (persistent) effects. More particularly, an acute encephalopathy is defined as an encephalopathy that is "sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)" and, in the case of children less than 18 months of age who present without an associated seizure event, the encephalopathy, is "indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). As to those children less than 18 months of age who present following a seizure (as in Kelli-Ann's case), the aids to interpretation instruct they shall be viewed "as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication." *Id.*

300aa-14(c) of the Vaccine Act – represents an impermissible (and inadequate) delegation of Congress' law-making functions to the Secretary.

II

The court cannot endorse either of petitioners' arguments – the first, because it misapprehends the basis of the special master's decision; the second because it raises an issue we lack the jurisdiction to decide. We discuss these arguments below.

To start with, petitioners assert that, because the Vaccine Act recognizes a claimant's right to seek relief for alleged vaccine-related injuries that do not meet the clinical criteria called out in the Vaccine Injury Table, it necessarily follows – so petitioners would argue – that the proof of such injuries may rest on clinical data different from that specified in the Vaccine Injury Table. And since the special master's decision allegedly failed to recognize and preserve this distinction, her decision is said to be wrong as a matter of law.

The problem with the argument is that it misapprehends the reasons that led the special master to reject their claim. The special master did not reject petitioners' claim for failing to meet the requirements of an acute encephalopathy as defined in the Vaccine Injury Table. That point is never mentioned in the special master's decision. Rather, the claim was rejected because it failed to meet any generally accepted definition of acute encephalopathy. A brief look at the evidence makes this clear.

At the hearing on their claim, petitioners offered the testimony of Dr. Marcel Kinsbourne, a board-certified pediatric neurologist currently serving as research professor at the Center for Cognitive Studies, Tufts University, Massachusetts. Dr. Kinsbourne's testimony, offered to a degree of medical certainty, was that Kelli-Ann's seizure disorder was due to an acute encephalopathy, experienced within 24 hours of the vaccine's administration, that was manifested through a period of seizure-related unconsciousness which endured for a period of thirty minutes. Additionally, Dr. Kinsbourne expressed the opinion that the multiple seizures Kelli-Ann experienced during that same time frame, even though punctuated with returns to full alertness, were also indicative of an acute encephalopathy.

Neither of these opinions carried the day. As noted earlier in this Order, the first position failed for lack of factual corroboration (the relevant medical records did not bear out the occurrence of a thirty-minute period of seizure-associated unconsciousness) and the second position was rejected on the basis of opposing expert opinion (the opinion of Dr. Fenichel declaring that multiple seizures interspersed with returns to full alertness presented a condition diagnostically distinguishable from prolonged unconsciousness).

The aforementioned grounds on which the special master's decision was based make clear that petitioners' claim was not rejected for failure to meet the criteria of a Table injury.

The petitioners' other argument – their contention that the Secretary's authority to revise the Vaccine Injury

Table represents an impermissible delegation of law-making authority – presents an issue we lack the power to decide.

Under the Vaccine Act, the Office of Special Masters is vested with authority to decide claims seeking compensation for alleged vaccine-caused injuries, 42 U.S.C. § 300aa-12(d)(3)(A), while this court, in turn, is charged with reviewing the decisions of that Office to insure their justifiability in fact and correctness in law, 42 U.S.C. § 300aa-12(e). Given these very specific and, indeed, very limited grants of power, neither forum – not the Office of Special Masters nor this court sitting as a reviewing body – may take up the contention that petitioners are attempting to raise here, namely, that they are entitled to have the merits of their claim evaluated under Table criteria different from those in place at the time the claim was first put forward. Such an assertion, while certainly related to a claim for compensation is not, in itself, *a* claim for compensation nor even a subordinate part of such a claim. It is, rather, the assertion of a wholly independent right the resolution of which demands the exercise of a judicial power substantially different in scope from the power to decide a particular claimant's entitlement to compensation under the Vaccine Act.

What petitioners seek is a declaratory judgment respecting the constitutional legitimacy of 42 U.S.C. § 300aa-14(c) – the statute that authorizes the Secretary to promulgate regulations modifying the Vaccine Injury Table. That relief raises an issue that is intimately tied to the power to review the Secretary's regulations and, as such, it is an issue appropriate for consideration by a United States court of appeals pursuant to Section

300aa-32 of the Vaccine Act.[2] *See Oklahoma v. Civil Service Comm'n*, 330 U.S. 127, 138-139 (1947) (recognizing that a court granted jurisdiction by statute to review the legality of administrative orders is also empowered to examine the constitutionality of the statute by virtue of which such orders were entered.) The issue lies beyond our jurisdiction to hear and decide.

III

For the reasons given, the decision of the special master is affirmed. Petitioners' motion for review is denied – in part for lack of merit and, in part, for lack of jurisdiction.

/s/ John P. Wiese
John P. Wiese
Judge

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[2] The referenced section, 42 U.S.C. § 300aa-32 reads as follows:

> A petition for review of a regulation under this part [referring to the Secretary's authority under 42 U.S.C. § 300aa-14(c)] may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

In the United States Court of Federal Claims

No. 96-63 V

FRANK AND LISA O'CONNELL AS LEGAL REPRESENTATIVES OF THEIR DAUGTHER, KELLI-ANN O'CONNELL,

(Filed May 27, 1998)

JUDGMENT

v.

SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES

Pursuant to the court's Order of May 13, 1998, affirming the special master's decision of February 2, 1998, denying petitioner's claim to compensation, and also denying petitioner's motion for review.

IT IS ORDERED AND ADJUDGED this date, pursuant to Appendix J ¶ 30, that the petition is dismissed – in part for lack of merit and, in part, for lack of jurisdiction. No costs.

David A. Lampen
Clerk of Court
By: /s/ Illegible
Deputy Clerk

May 27, 1998

NOTE: As to election, 90 days from this or the issuance of the appellate court's mandate, see Appendix J ¶ 33.

As to attorneys' fees and costs, within 21 days of the above election, see Appendix J ¶ 12.

As to petition for review, 60 days from this date, see Appendix J ¶ 32. Petition for review and filing fee of

$100.00 should be mailed to the following address: Clerk, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, NW, Washington, DC 20439.

United States Court of Appeals for the Federal Circuit

98-5134

FRANK and LISA O'CONNELL,
as legal representatives of their daughter,
Kelli-Ann O'Connell

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Judgment

ON APPEAL from the UNITED STATES COURT OF FEDERAL CLAIMS

in CASE NO(S). 96-VV-63

This CAUSE having been hard and considered, it is ORDERED and ADJUDGED:

AFFFIRMED [sic]

ENTERED BY ORDER OF THE COURT

DATED **NOV 01 1999**

/s/ Jan Horbaly, /ks
Jan Horbaly, Clerk

ISSUED AS A MANDATE:

FEBRUARY 9, 2000

United States Court of Appeals for the Federal Circuit

98-5134

FRANK and LISA O'CONNELL, as legal representatives of their daughter, Kelli-Ann O'Connell,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

ORDER

(Filed Feb. 2, 2000)

A petition for rehearing en banc having been filed by the APPELLANTS, and a response thereto having been invited by the court and filed by the APPELLEE, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on February 9, 2000.

FOR THE COURT,

/s/ Jan Horbaly
Clerk

Dated: February 2, 2000

cc: Brian A. O'Connell
Vincent J. Matanoski

O'CONNELL V HHS, 98-5134
(CFC – 96-VV-63)

42 U.S.C. § 300aa-14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I. DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).

Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis).....	3 days
C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days

D.	Residual seizure disorder in accordance with subsection (b)(2).....	3 days
E.	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A.	Anaphylaxis or anaphylactic shock	24 hours
B.	Encephalopathy (or encephalitis).....	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C.	Residual seizure disorder in accordance with subsection (b)(2).....	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).

	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	– in a non-immunodeficient recipient.....	30 days
	– in an immunodeficient recipient.....	6 months
	– in a vaccine-associated community case.....	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours

B.	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.....	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a) of this section:

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete, hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if –

(A) in the case of a measles, mumps, or rubella vaccine or any combination of

such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented

by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa-11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d) of this section, such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine

Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following –

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) of this section or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Recommendation

The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table.

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42 U.S.C. § 300aa-14 (amended Dec. 19, 1989)

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) of this section to include –

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) of this section to include –

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

PUBLIC LAW 99-660-Nov. 14, 1986 - 100 Stat. 3779

SEC. 312. RELATED STUDIES.

(a) REVIEW OF PERTUSSIS VACCINES AND RELATED ILLNESSES AND CONDITIONS. - Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

(1) Hemolytic anemia.

(2) Hypsarrhythmia.

(3) Infantile spasms.

(4) Reye's syndrome.

(5) Peripheral mononeuraopathy.

(6) Deaths classified as sudden infant death syndrome.

(7) Aseptic meningitis.

(8) Juvenile diabetes.

(9) Autism.

(10) Learning disabilities.

(11) Hyperactivity.

(12) Such other illnesses and conditions as the Secretary may choose to review or as the Advisory Commission on Childhood Vaccines established under

section 2119 of the Public Health Service Act recommends for inclusion in such review.

The review under this subsection shall include notice and opportunity for a public hearing, consideration of written information submitted by the public, and consultation with such Advisory Commission.

(b) FINDINGS WITH RESPECT TO PERTUSSIS. – Not later than 3 years after the effective date of this title, the Secretary shall make, and publish in the Federal Register, the following specific findings;

(1) Whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated by pertussis-containing vaccines.

(2) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), the circumstances under such causation or aggravation can reasonably be determined to occur.

(3) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), and for each illness or condition set forth in the Vaccine Injury Table under section 2114 of the Public Health Service Act, the time periods within which the first symptom or manifestation of onset or aggravation of each such illness or condition can reasonably be determined to occur after pertussis vaccination.

(c) REVISION OF TABLE WITH RESPECT TO PERTUSSIS VACCINES. – At the same time the Secretary publishes in the Federal Register findings under subsection (b), the Secretary shall propose regulations to amend the Vaccine Injury Table under section 2114 of the Public Health Service Act as a result of such findings. Not later than 42 months after the effective date of this title, the Secretary shall promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

(d) REVIEW OF MMR VACCINES AND RELATED ILLNESSES AND CONDITIONS. – Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review similar to the review conducted under subsection (a) with respect to the potential relationship between vaccines containing rubella (including MMR) and radiculoneuritis. The review under this subsection shall include notice and opportunity for a public hearing, consultation with the Advisory Commission on Childhood Vaccines and consideration of written information submitted by the public. Not later than 3 years after the effective date of this title, the Secretary shall make and publish in the Federal Register findings similar to those required by subsection (b) and shall, if appropriate, propose similar regulations (and thereafter promulgate such regulations) to those required by subsection (c), with respect to compensation under the National Vaccine Injury Compensation Program established under section 2110 of the Public Health Service Act for radiculoneuritis caused, contributed to, or significantly aggravated by vaccines containing rubella.

(e) PERTUSSIS AND MMR STUDIES. –

(1) In order to assist the Secretary in making the findings required under subsections (b) and (d), the Secretary shall, in accordance with subparagraph (B), arrange for the conduct of studies of –

(A) the relationship between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the illnesses or conditions set forth in paragraphs (1) through (11) of subsection (a),

(B) the relationship between vaccines containing pertussis and any other illnesses and conditions, as selected by the Secretary or the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act, and

(C) the relationship between vaccines containing rubella (including MMR) and radiculoneuritis.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the studies required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct

such study and prepare and submit the reports thereon as provided in paragraph (3).

(C) The Institute of Medicine or other group or association conducting the studies required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act.

(3) Reports on the results of the studies required by paragraph (1) shall be completed and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary not later than 32 months after the effective date of this title. Upon submission to the Secretary, the reports shall be made available to the public.

(4) There are authorized to be appropriated such sums as are necessary for the purpose of making payments for the conduct of the studies required under this subsection.

(f) DEFINITIONS. – For purposes of this section:

(1) The term "medical and scientific information" includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official Government publications, as well as relevant unpublished information, data, studies, and observations.

(2) The term "MMR" means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella disease.

42 C.F.R.

SUBCHAPTER I – (RESERVED)
SUBCHAPTER J – VACCINES

PART 100 – VACCINE INJURY COMPENSATION

Sec.

100.1 Applicability.

100.2 Average cost of a health insurance policy.

100.3 Vaccine injury table.

AUTHORITY: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act. 100 Stat. 3767, as amended (42 U.S.C. 300aa-15); § 100.3, the Vaccine Injury Table, issued under sec. 312 of Pub. L. 99-660. 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and sec. 2114(c) of the PHS Act (42 U.S.C. 300aa-14(c)).

§ 100.1 Applicability.

This part applies to the National Vaccine Injury Compensation Program (VICP) under subtitle 2 of title XXI of the Public Health Service (PHS) Act.

[60 FR 7693, Feb. 8, 1995]

§ 100.2 Average cost of a health insurance policy.

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS Act, 42 U.S.C. 300aa.15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting

lost earnings, less certain deductions. One of the deductions is the average cost of a health insurance policy, as determined by the Secretary of Health and Human Services. The Secretary has determined that the average cost of a health insurance policy is $158.00 per month. This amount will be revised to reflect the changes in the medical care component of the Consumer Price Index (All Urban Consumers, U.S. City Average), published by the United States Bureau of Labor Statistics, plus 2 percent per year. The revised amounts will be effective upon their delivery by the Secretary to the United States Claims Court, and the amounts will be published in a notice in the Federal Register from time to time as determined by the Secretary.

[57 FR 28099, June 24, 1992, as amended at 60 FR 7693, Feb. 8, 1996]

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. DTP; P; DT; Td; or Tetanus Toxoid; or in any combination with Polio; or any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Pertussis Bacteria, or Specific Pertussis Antigen(s):	
A. Anaphylaxis or anaphylacic shock	4 hours.
B. Encephalopathy (or encephalitis)	72 hours.
C. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
II. (a). Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component:	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
C. Residual seizure disorder in accordance with subsection (b)(3)	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
D. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

VACCINE INJURY TABLE

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
II. (b). In the case of measles, mumps, rubella (MMR), measles, rubella (MR) or rubella vaccines only:	
A. Chronic Arthritis	42 days.
B. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Polio Vaccine (other than inactivated Polio Vaccine):	
A. Paralytic Polio	
In a non-immunodeficient recipient	30 days.
In an immunodeficient recipient	6 months.
In a vaccine associated community case	Not applicable.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Inactivated Polio Vaccine:	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

(1) *Anaphylaxis and anaphylactic shock.* For purposes of paragraph (a) of this section: Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) *Encephalopathy.* For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization.

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) *For adults and children 18 months of age or older,* an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) *Residual Seizure Disorder.* (i) A petitioner may be considered to have suffered a residual seizure disorder for purposes of paragraph (a) of this section, if the first seizure or convulsion occurred 5-15 days (not less than 5 days and not more than 15 days) after administration of the vaccine and 2 or more additional distinct seizure or convulsion episodes occurred within 1 year after the administration of the vaccine which were unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit). A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and

qualified expert neurological testimony is presented to the contrary in a particular case.

(ii) For purposes of paragraph (a) of this section, a petitioner shall not be considered to have suffered a residual seizure disorder, if the petitioner suffered a seizure or convulsion unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit) before the fifth day after the administration of the vaccine involved.

(4) *Seizure and convulsion.* For purposes of paragraphs (b)(2) and (3) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) *Sequela.* The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vascultitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction) metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(c) *Effective date provisions.* The Table of Injuries set forth in paragraph (a) of this section applies to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 10, 1995. The Qualification and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions filed with the United States Court of Federal Claims on or after March 10, 1995. The petitions for compensation filed with the United States Court of Federal Claims before

March 10, 1995 shall be governed by section 2114(a) (initial "Table") and section 2114(b) (initial "Qualification and Aids to Interpretation") of the Public Health Service Act as in effect on February 3, 1995.

[50 FR 7594, Feb. 8, 1995]

United States Court of Appeals
for the Federal Circuit

98-5161

MICHELE Y. TERRAN,
as legal representative of Julie F. Terran, a minor,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

DECIDED: October 27, 1999

Before PLAGER, LOURIE, and CLEVENGER, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* CLEVENGER. Dissenting opinion filed by *Circuit Judge* PLAGER.

CLEVENGER, *Circuit Judge.*

Michele Terran appeals from the judgment by the United States Court of Federal Claims sustaining the Special Master's decision to deny compensation to Julie F. Terran under the National Child Vaccine Injury Act of 1986 (the "Vaccine Act" or "Act"). *See Terran v. Secretary of Dept. of Health & Human Services,* No. 95-451V (Fed. Cl. 1998). Terran argues that the Vaccine Injury Table applied by the Special Master to her claim is invalid because the statutory scheme pursuant to which it was created is unconstitutional, and also that the Court of Federal Claims erred both legally and factually in sustaining the

Special Master's ruling. We hold, however, that the Vaccine Act does not violate separation of powers principles, and that the Court of Federal Claims committed no reversible error. We therefore affirm.

I

This appeal raises three issues: (i) whether the Court of Federal Claims has jurisdiction to adjudicate constitutional challenges to the validity of the current Vaccine Injury Table, which was promulgated by the Secretary pursuant to 42 U.S.C. § 300aa-14(c) and which became effective on March 10, 1995 (the "1995 Table"); (ii) whether the section of the Vaccine Act that authorizes the Secretary to create the 1995 Table, *see* 42 U.S.C. § 300aa-14(c) (1994), violates separation of powers principles found in the Constitution; and (iii) whether the Court of Federal Claims erred in sustaining the Special Master's decision to deny Julie compensation under the Vaccine Act.

A

The relevant facts are not in dispute. Julie Terran was born on February 10, 1992, in Phoenix, Arizona, and was discharged in good health from the hospital the next day. Julie received her first diphtheria-pertussis-tetanus ("DPT") vaccination when she was two months old, and her second DPT vaccination when she was three and one-half months old. On August 10, 1992, when Julie was six months old, she received her third DPT vaccination. Julie received her fourth DPT vaccination on September 22, 1993. All of the vaccinations were given by Dr. Gary

Berebitsky, Julie's pediatrician, at her well-baby care checkup examinations. The first three DPT vaccines utilized whole cell pertussis bacteria, whereas the fourth was an acellular DPT vaccine. Julie's third vaccination, which occurred on August 10, 1992, is the basis for this dispute.

On August 11, 1992, the day after her third DPT vaccination, Julie experienced a seizure lasting approximately seven seconds which caused one of her arms to become stiff. The next day, August 12, Julie suffered four afebrile seizures, each lasting roughly one minute in length. Immediately after the seizures, Julie was rushed by ambulance to Phoenix Children's Hospital, where she was admitted. On August 13, in the presence of hospital personnel, Julie suffered another seizure lasting approximately five and one-half minutes. Hospital personnel then administered the anti-convulsant drug Phenobarbital to Julie. In the seven days following Julie's third DPT vaccination, she experienced a total of approximately twelve minutes of seizure activity. On September 12, roughly one month after the vaccination in question, Julie suffered a seizure lasting 50 minutes even though she was on Phenobarbital at the time. Julie's seizures continue to this day.

On September 13, 1993, Dr. Berebitsky noted that Julie was "well appearing" and "neurologically intact." However, in November 1993, he noted a problem with Julie's neurological condition, indicating that she scored a borderline passing grade on the Denver Developmental Screening Test. Julie is currently mentally retarded.

Julie also had a meningocele lump removed from her skull as a young child. Prior to her third DPT vaccination, Julie's doctors conducted several tests to determine whether she suffered any permanent brain damage as a result of the lump. These tests concluded that she had no brain abnormalities. An MRI scan conducted on May 18, 1992, showed that Julie had normal brain structure, and a test showed that there was no cancer in the removed lump. A certified pediatric neurosurgeon conducted a follow-up on Julie's surgery and found her neurological condition to be unremarkable except for moderate strabismus. Two MRI's conducted after Julie's third vaccination showed that she had no structural pathology in her brain. In connection with Terran's claim for compensation under the Vaccine Act, the Government requested that Julie undergo two separate genetic workups, both of which showed normal results.

B

Childhood vaccinations, though an important part of the public health program, are not without risk. Because vaccines often contain either killed bacteria or live but weakened viruses, they can cause serious adverse effects. *See O'Connell v. Shalala*, 79 F.3d 170, 172 (1st Cir. 1996) (citing Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines 1 (1991)). Despite the relatively rare occurrence of such problems, Congress became concerned that tort liability and related costs might drive up the prices of vaccines and discourage vaccine manufacturers from staying in this market, and that normal tort litigation might leave

many sufferers of vaccine-caused injuries uncompensated. *See* H.R.Rep. No. 99-908, at 1, 4, 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344, 6345, 6347-48; *see also O'Connell*, 79 F.3d at 172-73.

Accordingly, in 1986, Congress passed the National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, 1986 U.S.C.C.A.N. (100 Stat.) 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (1994)), which established a program administered by the Secretary of Health and Human Services ("Secretary") to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-1 (1994). As part of this program, Congress established a Vaccine Injury Compensation Program through which claimants could petition to receive compensation for vaccine-related injuries or death. *See id.* § 300aa-10(a). To receive compensation, a claimant must petition the Court of Federal Claims and demonstrate by a preponderance of the evidence either that (i) the vaccinated child suffered an injury listed on a table, or a complication or "sequela" thereof; or (ii) that the vaccine caused or significantly aggravated the child's injury or condition. *See id.* §§ 300aa-11, -13 to -14; 42 C.F.R. § 100.3 (1996). Thus, the Vaccine Act provides two possible ways for a claimant to receive compensation: first, by showing that she suffered a "table injury," or second, by proving causation in fact.[1]

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[1] However, the Vaccine Act does not preclude traditional tort remedies. A person claiming injury due to a vaccine is required to seek redress first through the Vaccine Act, but if she is not satisfied with the result, she may reject the judgment and litigate her claim in federal or state courts, subject to certain limitations imposed by the Vaccine Act. *See* 42 U.S.C. §§ 300aa-11(a), 300aa-21 (1994); *Schafer v. American Cyanamid*

The Vaccine Act establishes an Office of Special Masters within the United States Court of Federal Claims to decide petitions for compensation, provides for review of a Special Master's decision by the Court of Federal Claims, and allows appeal of the Court of Federal Claims's rulings to this court. *See* 42 U.S.C. § 300aa-12 (1994).

To aid the Vaccine Program's goal of providing efficient compensation for vaccine injuries, Congress provided, in the form of a table, a list of vaccines, a parallel list of adverse medical conditions commonly associated with the use of each vaccine, and, for certain medical conditions, a time period in which the first symptoms should become apparent following vaccination. *See id.* § 300aa-14(a). These listings comprise the initial Vaccine Injury Table (the "Initial Table"), and are to be read in conjunction with a separate subsection, the "Qualifications and aids to interpretation" (the "QAIs"), that provides explanations and definitions for terms used in the Initial Table. *Id.* § 300aa-14(b). To demonstrate a table injury, a claimant must prove that within the prescribed time period following a vaccination, she suffered one of the disorders set forth on the Vaccine Injury Table corresponding to the vaccine administered. If she cannot make this showing, she must instead prove causation in fact. For example, with respect to a DPT vaccine, the Initial Table grants recovery if the claimant suffers, *inter alia*, a first symptom of, or a first manifestation of onset of, "residual seizure disorder" or "encephalopathy" within

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Co., 20 F.3d 1, 2-3 (1st Cir. 1994) (discussing the relation between the Vaccine Act and the traditional tort system).

three days of receiving the vaccine. *See id.* The QAIs define "encephalopathy" to mean "any significant acquired abnormality of, or injury to, or impairment of function of the brain," and set forth certain symptoms or manifestations of an encephalopathy. *Id.* § 300aa-14(b)(3)(A).

Congress included the Initial Table in the Vaccine Act legislation, rather than delegating the creation of the first injury table to the Secretary, because it was concerned that the administrative process would significantly delay the implementation of the Vaccine Compensation Program. *See* Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce, 98th Cong. 210-11 (1984) (letter from Martin H. Smith, Vice President, American Academy of Pediatrics to Representative Henry A. Waxman). Congress intended the Secretary to revise and update the Initial Table with more accurate information that would become available as a result of the research on vaccine injuries mandated by the Vaccine Act. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-81 (requiring the Secretary to make findings on the accuracy of the Initial Table with respect to, *inter alia*, pertussis vaccines and to propose regulations to modify the Initial Table accordingly); H.R.Rep. No. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Thus, the Vaccine Act gives the Secretary the express power to promulgate regulations that modify the Table by adding to, or deleting from, the list of compensable disorders and by revising the time periods contained in the Table. *See* 42 U.S.C. § 300aa-14(c)(3) (1994). The Vaccine Act requires

the Secretary to make such modifications pursuant to notice and comment rulemaking, and to provide at least 180 days for public comment and an opportunity for a public hearing. *See id.* § 300aa-14(c)(1). In addition, the Act provides that if the Initial Table is modified, the original QAIs cease to apply unless the modified Table expressly states that they remain valid. *See id.* § 300aa-14(c)(4). In February 1995, the Secretary promulgated regulations creating the current Vaccine Injury Table (the "1995 Table") and associated new QAIs, which became effective on March 10, 1995. *See* 42 C.F.R. § 100.3 (1996). As relevant to this case, the 1995 Table and associated QAIs deleted residual seizure disorder ("RSD") from the list of compensable table injuries related to DPT vaccine and significantly narrowed the definition of "encephalopathy." The 1995 Table and the modified QAIs apply to all petitions filed on or after their effective date of March 10, 1995. *See* 42 U.S.C. § 300aa-14(c)(4) (1994).

C

Terran filed a petition for compensation with the Court of Federal Claims on July 12, 1995. The petition alleged that Julie's third DPT vaccination, administered on August 10, 1992, caused Julie to suffer both RSD and encephalopathy. Because the 1995 Table does not list RSD as a compensable injury associated with DPT vaccine, the Special Master concluded that Terran must establish causation in fact to prevail on this count. With respect to encephalopathy, Terran conceded that Julie's disorder did not meet the definition of an encephalopathy as set forth in the revised QAIs, and the Special Master accordingly

concluded that Terran could prevail only if she demonstrated causation in fact for this illness as well. *See Terran v. Secretary of Health & Human Servs.*, No. 95-451V, slip op. at 8-9 (Fed. Cl. (Special Master) Jan. 23, 1998). After examining the medical records and testimony, the Special Master determined that Terran failed to establish a *prima facie* case of causation in fact for either of Julie's conditions and denied compensation. *See id.* at 18.

Terran sought review of the Special Master's findings in the Court of Federal Claims. In her motion for review, Terran first alleged that the Vaccine Act is unconstitutional insofar as it authorizes the Secretary to modify the statutorily-enacted Initial Table found at 42 U.S.C. § 300aa-14(a) via administrative rulemaking. Second, Terran argued that even if the 1995 Table was valid, the Special Master erred in applying it to Julie's case and that he improperly rejected her theory of causation in fact under *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579 (1993). The Court of Federal Claims held that it was without jurisdiction to consider Terran's constitutional challenge, and sustained the Special Master's decision in all respects. *See Terran*, No. 95-451V, slip op. at 5, 10. Terran then petitioned for review to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

II

We consider first the Court of Federal Claims's ruling that it does not have jurisdiction to consider appellant's constitutional challenge to the Vaccine Act. We review

questions involving the jurisdiction of the Court of Federal Claims *de novo*. *See Widdoss v. Secretary of Health & Human Servs.*, 989 F.2d 1170, 1174 (Fed. Cir. 1993). Determining the jurisdiction of the Court of Federal Claims necessarily involves statutory interpretation, which we likewise review *de novo*. *See Munn v. Secretary of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992); *Neher v. Secretary Health & Human Services*, 984 F.2d 1195, 1197-98 (Fed. Cir. 1993).

A

The Court of Federal Claims found that it lacked jurisdiction on two grounds. Reciting the well-known fact that it only has jurisdiction to hear claims against the Government for money damages, the court ruled that Terran's argument that the Vaccine Act violated the Presentment Clause of the Constitution, *see* U.S. Const. art. I, § 7, cl. 2, was not based on a "money mandating provision" of the Constitution, thereby depriving it of jurisdiction. *See Terran v. Secretary of Health & Human Servs.*, No. 95-451V, slip op. at 5 (Fed. Cl. July 10, 1998) (citing *Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980)).

It is well understood that the Court of Federal Claims, like all federal courts, is a court of limited jurisdiction. Its jurisdiction is defined by the Tucker Act, which gives that court authority to

> render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or

> for liquidated or unliquidated damages in cases not sounding in tort.

28 U.S.C. § 1491(a)(1) (1994). The Supreme Court has interpreted this language to mean that a plaintiff who seeks redress in the Court of Federal Claims must present a claim for "actual, presently due money damages from the United States." *United States v. King*, 395 U.S. 1, 3 (1969); *see also United States v. Testan*, 424 U.S. 392, 400 (1976). Although the Tucker Act provides jurisdiction for damage suits against the United States Government, it is equally clear that the Tucker Act does not itself create a cause of action against the Government. Rather, a plaintiff seeking recovery against the Government in the Court of Federal Claims must point to a money-mandating constitutional provision, statute, regulation, or contract with the United States affording it a right to money damages. *See United States v. Mitchell*, 463 U.S. 206, 216-17 (1983); *Loveladies Harbor, Inc. v. United States*, 27 F.3d 1545, 1554 (Fed. Cir. 1994) (en banc); *United States v. Connolly*, 716 F.2d 882, 885 (Fed. Cir. 1983) (en banc).

We think that the Court of Federal Claims misconstrued the scope of its jurisdiction. The Presentment Clause of the Constitution states that before becoming law, a legislative act must be approved by both houses of Congress and must be presented to the President of the United States for approval. *See* U.S. Const. art. I, § 7, cl. 2. We agree that this constitutional provision neither explicitly nor implicitly obligates the federal Government to pay damages, and accordingly is not by itself actionable in the Court of Federal Claims. *Cf. Connolly*, 716 F.2d at 887 (holding that the First Amendment does not by itself give rise to a cause of action for damages); *Carruth v.*

United States, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (holding that claims based on the Fifth Amendment's Due Process and Equal Protection clauses do not give rise to jurisdiction under the Tucker Act); *Walton v. United States*, 213 Ct. Cl. 755, 757 (1977). When determining jurisdiction, however, we must look to the true nature of the underlying action. *See Katz v. Cisneros*, 16 F.3d 1204, 1207 (Fed. Cir. 1994); *Livingston v. Derwinski*, 959 F.2d 224, 225 (Fed. Cir. 1992). Here, Terran's claim for relief is based on the Vaccine Act and is a claim for money – that is, compensation under the Act. Therefore, the Vaccine Act is the "Act of Congress" which forms the basis of Terran's claim, and there is little dispute that such a claim is one for presently due money damages. Indeed, we note that the Vaccine Act itself gives jurisdiction to the Court of Federal Claims to determine whether Terran is entitled to compensation, independent of the Tucker Act. *See* 42 U.S.C. § 300aa-12(a) (1994).

Because jurisdiction is proper, the Court of Federal Claims had the power to address Terran's argument based on the Constitution. *See Beck v. Secretary*, 924 F.2d 1029, 1036 (Fed. Cir. 1991) ("It is, however, reasonable to infer that the [Vaccine] Act must confer on the Claims Court that power which is necessary to adjudicate the controversy before it."); *compare Connolly*, 716 F.2d at 887 (holding that the Court of Claims did not have jurisdiction over plaintiff's First Amendment claim of improper removal) *with Jackson v. United States*, 428 F.2d 844, 846 (Ct. Cl. 1970) (holding that the Court of Claims did have jurisdiction over plaintiff's statutory claim for back pay, including arguments based on the First Amendment). We

are therefore convinced that Terran's claim for compensation under the Vaccine Act properly lies within the jurisdiction of the Court of Federal Claims, unless ousted on the second ground decided by the court.

B

The Court of Federal Claims also held that a provision in the Vaccine Act providing for immediate judicial review of rules promulgated under the Act precluded it from reviewing Terran's challenge to the validity of the 1995 Table. That statutory review provision states:

> A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

42 U.S.C. § 300aa-32 (1994). The Court of Federal Claims held that this provision requires a party challenging regulations promulgated under the Act to raise such challenges within 60 days if the factual basis for such a challenge existed at that time. *See Terran v. Secretary of Dept. of Health & Human Services*, No. 95-451V slip op. at 5 (Fed. Cl. July 10, 1998). Because Julie experienced seizures as early as 1992 and had a diagnosed neurological condition by November 1993, the court held that Terran could have challenged the 1995 Table in March 1995, when it was promulgated, and was barred from doing so now. *See id.*

Again, we disagree with the jurisdictional analysis by the Court of Federal Claims. The first and most important

step when interpreting a statute is, of course, analyzing its text. It is significant that the language of section 300aa-32 conferring jurisdiction on federal appellate courts is permissive in nature – parties may file a petition for review of regulations promulgated under the Vaccine Act in the courts of appeals within 60 days of their enactment. The statutory language does not explicitly require a party to challenge regulations under the Vaccine Act within such time period and in such a forum. Therefore, we cannot say that Congress clearly intended to limit judicial review to the 60-day period. The language in section 300aa-32 thus differs from the mandatory language found in some other statutory review clauses. *See Eagle-Picher Industries v. EPA*, 759 F.2d 905, 911 (D.C. Cir. 1985) (holding that a statutory provision of CERCLA clearly foreclosing later judicial review of matters that could have been raised in the ninety day statutory period bars a later challenge).

Nevertheless, we recognize that there are cases in which courts have held that statutory review provisions specifying a limited time period for challenging regulations in a particular forum preclude later challenges to those regulations. The District of Columbia Circuit, for example, has held that statutory time limits on review of agency rulemaking can foreclose subsequent challenges to those rules. *See, e.g., Eagle-Picher*, 759 F.2d at 911; *Natural Resources Defense Council v. NRC*, 666 F.2d 595, 601-03 (D.C. Cir. 1981). These cases, however, do not support the Government's broad contention that review of vaccine regulations is never proper after expiration of the 60-day statutory review period. In *Eagle-Picher*, for example, the statutory provision at issue was section

113(a) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 ("CERCLA") which, as already mentioned, specifically stated that agency rules had to be challenged within 90 days, and any matter which could have been raised in that time period was not subject to later judicial review. *See* 42 U.S.C. § 9613(a) (1982); *Eagle-Picher*, 759 F.2d at 911. More importantly, the case law provides several exceptions under which subsequent judicial review of a regulation would still be proper. *See Public Citizen v. NRC*, 901 F.2d 147, 152 & n. 1 (D.C. Cir. 1990); *NLRB Union v. Federal Labor Relations Auth.*, 834 F.2d 191, 195-96 (D.C. Cir. 1987); *Eagle-Picher*, 759 F.2d at 913-14 & n. 45; *Natural Resources Defense Council*, 666 F.2d at 602 & nn. 47-49. One important exception is that when a party seeks to challenge a regulation on substantive grounds of invalidity, such as that the regulation was not authorized by legislation, review may still be had. *See Public Citizen*, 901 F.2d at 152 & n. 1; *Natural Resources Defense Council*, 666 F.2d at 602. This is especially true when the subsequent challenge occurs in an agency enforcement proceeding. *See NLRB Union*, 834 F.2d at 195-196 ("As applied to rules and regulations, the statutory time limit restricting judicial review of [agency] action is applicable only to cut off review directly from the order promulgating a rule. It does not foreclose subsequent examination of a rule where properly brought before this court for review of further [agency] action applying it.") (quoting *Functional Music, Inc. v. FCC*, 274 F.2d 543, 546 (D.C. Cir. 1958)); *see also Cronin v. FAA*, 73 F.3d 1126, 1131 n. 3 (D.C. Cir. 1996) (stating that airline pilots could challenge the legality of

an FAA regulation in subsequent enforcement actions against them).

Terran's claim in this case – that the 1995 Table is an invalid regulation because that section of the Vaccine Act authorizing its creation is unconstitutional – is a substantive challenge to the validity of the 1995 Table. In addition, the Special Master clearly applied the 1995 Table to Terran's claim for compensation in an adjudication, which in many ways is similar to the agency actions discussed in *NLRB Union* and *Functional Music*. Therefore, even if section 300aa-32 generally bars subsequent litigation over the validity of vaccine regulations, Terran falls within both well established exceptions identified above. We therefore conclude that 42 U.S.C. § 300aa-32 does not preclude the Court of Federal Claims from exercising jurisdiction over Terran's substantive challenge to the validity of the 1995 Table.

III

We turn next to the substance of Terran's constitutional challenge to the Vaccine Act. Terran raises two theories as to why 42 U.S.C. § 300aa-12(c), which authorizes the Secretary to promulgate a revised Vaccine Injury Table, is unconstitutional. First, Terran claims that section 300aa-12(c) authorizes the Secretary to amend part of a statute, namely the Vaccine Injury Table found in section 300aa-12(a), via administrative rulemaking, and therefore contravenes the Presentment Clause of the Constitution. *See* U.S. Const. art. I, § 7, cl. 2. Alternatively, Terran contends that the Vaccine Act effects an unconstitutional delegation of legislative authority to the Secretary.

A

The Presentment Clause requires, in relevant part, that "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it becomes a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it," U.S. Const. art. I, § 7, cl. 2. There is no dispute that the Secretary's actions here did not fulfill the bicameralism and presentment conditions required of legislative acts by the Presentment Clause; the only question, therefore, is whether the Presentment Clause applies to the Secretary's promulgation of the regulation establishing the 1995 Table.

The Presentment Clause is inapplicable to administrative rulemaking in general, of course, because rulemaking is by definition not a legislative act, but rather an exercise of executive function properly entrusted to administrative agencies. *See, e.g., American Trucking Assns., Inc. v. United States*, 344 U.S. 298, 310-13 (1953). Nevertheless, because the Initial Table was made a part of the Vaccine Act, *see* 42 U.S.C. § 300aa-14(a) (1994), Terran insists that the Secretary's power to modify the Table effectively allows her to amend or repeal part of a statute, and thus violates the Presentment Clause. Terran argues that this result is dictated by the Supreme Court's decisions in *Clinton v. New York*, 524 U.S. 417 (1998), in which the Court held that the Line Item Veto Act violates the Presentment Clause, and *INS v. Chadha*, 462 U.S. 919, 954-59 (1983), in which the Court struck down a legislative veto provision in a statute.

The Constitution does not authorize members of the executive branch to enact, amend, or repeal statutes. *See Clinton*, 524 U.S. at 438. Instead, this legislative power is vested exclusively in Congress, and the exercise of such legislative power must follow the procedures set forth in the Constitution. *See Chadha*, 462 U.S. at 954 ("Amendment and repeal of statutes, no less than enactment, must conform with Ar[ticle] I."). The critical question in this case is therefore whether the Secretary's action in promulgating the 1995 Table should properly be understood as an amendment or a repeal of an existing law.

We are convinced that the Vaccine Act does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations as contemplated in the Act. First, as a formal matter, the Act does not in fact allow the Secretary to explicitly amend the Initial Table. Although we acknowledge that the statutory language in section 300aa-14(c) refers to the Secretary's ability "to modify" and "to amend" the Vaccine Injury Table, 42 U.S.C. § 300aa-14(c)(1), (2) (1994), a closer reading of that section makes clear that when the Secretary acts pursuant to section 300aa-14(c), she does not change in any way the original injury table found in section 300aa-14(a), but rather promulgates an entirely new vaccine injury table. This new table applies only prospectively. *See* 42 U.S.C. § 300aa-14(c)(4) (1994). The Initial Table remains codified and unaltered, and continues to apply to all petitions filed before the revision. Therefore, the Initial Table is not amended.

Realizing this, Terran argues instead that the Act *effectively* allows the Secretary to amend the Initial Table.

However, we are not persuaded that the regulatory regime established by the Vaccine Act raises concerns under the Presentment Clause. When it created the Vaccine Act, Congress realized that the Initial Table contained flaws. *See, e.g.*, H.R.Rep. No. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Congress therefore directed the Secretary to commission studies on the link between vaccines and injuries, and created a panel to oversee the collection of data on vaccine related injuries. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660 §§ 312-13, 100 Stat. 3755, 3779-82 (1986); 42 U.S.C. § 300aa-19 (1994). Congress directed the Secretary to revise the Initial Table based on the information obtained from such studies. *See, e.g.*, National Childhood Vaccine Injury Act of 1986, 100 Stat. at 3779-80. Congress therefore clearly intended that the Initial Table would cease to apply to newly filed petitions when the Secretary promulgated a revised injury table. *See id.* § 300aa-14(c)(4). This aspect of the Vaccine Act is similar to "sunset" provisions that Congress routinely includes in legislation to specify the date on which a particular piece of legislation ceases to have effect. *See, e.g.*, 28 U.S.C.A. § 599 (West Supp. 1999) (specifying that Title 28, Chapter 40 of the United States Code – authorizing the appointment of independent counsels – ceases to be effective five years after the date of enactment of the Independent Counsel Reauthorization Act of 1994). Here, of course, the Vaccine Act does not specify a date certain on which the Initial Table becomes ineffective; instead, the Secretary's promulgation of a revised injury table triggers the ineffectiveness of the Initial Table. Because Congress itself decided to render the Initial Table ineffective upon

the Secretary's action, this statutory design does not violate the Presentment Clause. *See Clinton*, 524 U.S. at 446 & n. 40 (stating that the Supreme Court's power to "repeal" laws by promulgating rules of procedure for the lower federal courts does not run afoul of the Presentment Clause because "Congress itself made the decision to repeal prior rules upon the occurrence of a particular event – here, the promulgation of procedural rules by this Court").

The Supreme Court's recent decision in *Clinton v. New York* is not to the contrary. In holding the Line Item Veto Act unconstitutional in *Clinton*, the Court identified three factors distinguishing that statute from the one at issue in *Field v. Clark*, 143 U.S. 649 (1892), in which the Court upheld the constitutionality of the Tariff Act of 1890 that authorized the President to suspend legislatively-enacted import duty exemptions on certain goods whenever he felt that the exporting country was treating United States products unfairly. *See Clinton*, 524 U.S. at 442-43; Act of Oct. 1, 1809, § 3, 26 Stat. 612. First, the Court noted that the President's suspension power under the Tariff Act was contingent on conditions that did not exist when that law was passed, whereas the five-day time limit for canceling an appropriations line item under the Line Item Veto Act meant that the President's action was necessarily based on the same conditions contemplated by Congress. *See id.* at 443. In the Vaccine Act, as in the Tariff Act, Congress anticipated that the facts underlying its legislation might change in the future. *See, e.g.*, 42 U.S.C. § 300aa-19 (1994) (establishing the Advisory Commission on Childhood Vaccines and directing it to compile information relating to vaccine injury statistics),

§ 300aa-14(d) (1994) (requiring the Secretary to solicit comments from the Advisory Commission before promulgating a revised injury table). As a result, Congress intended the Secretary to promulgate revised injury tables when more accurate information linking vaccines to injuries became available. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-360, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-80.

Second, the *Clinton* Court noted that the Line Item Veto Act provided little constraint on the President's discretion to cancel a particular appropriation line item, whereas his discretion was much more channeled under the Tariff Act. *See Clinton*, 524 U.S. at 443-44. This factor also suggests that the delegation of power found in the Vaccine Act is proper. Although the Secretary ultimately has the discretion to either promulgate a revised table or not, Congress set forth detailed procedures and substantive considerations in the Vaccine Act that channel this discretion. For example, the Act requires the Secretary to respond to petitions made by "[a]ny person" to modify the vaccine injury table, unless the petition is clearly frivolous. 42 U.S.C. § 300aa-14(c)(2) (1994). Importantly, the Act sets forth both procedural requirements that govern regulations to modify the injury table, *see* 42 U.S.C. § 300aa-14(c)(1) (requiring notice and comment rulemaking, a 180-day comment period, and opportunity for a public hearing), advisory bodies that the Secretary is required to consult, *see id.* § 300aa-14(d) (requiring the Secretary to solicit input from the Advisory Commission), and substantive requirements for the revised injury tables, *see id.* § 300aa-14(e) (requiring the Secretary to

revise the vaccine injury table to include all recommended childhood vaccines).

Finally, the *Clinton* Court considered it important that the President was fulfilling Congress's policy under the Tariff Act when he suspended certain import duty exemptions, whereas he was clearly contravening Congress's policy judgment when he canceled spending items under the Line Item Veto Act. *See Clinton*, 524 U.S. at 444. The brief outline of the Vaccine Act already provided above demonstrates compellingly that the Secretary was executing congressional policy when she promulgated the 1995 Table. Indeed, the Act explicitly directed the Secretary to study pertussis vaccines and to promptly promulgate a revised injury table based on such findings. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-360, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-80. Thus, we conclude that the Secretary's actions in this case are controlled by *Field v. Clark*, rather than *Clinton*.

Under section 300aa-14(c) of the Vaccine Act, the Secretary does not have power to amend the original, legislatively-enacted Vaccine Injury Table. Instead, the Secretary merely has the power to promulgate revised injury tables that reflect current knowledge linking childhood vaccines to injuries. Congress intended that these improved tables provide the basis for compensation under the Act. We therefore conclude that section 300aa-14(c) of the Vaccine Act does not violate the Presentment Clause.

B

We next consider Terran's argument that, by granting the Secretary the power to promulgate revised vaccine injury tables, the Vaccine Act effects an unconstitutional delegation of legislative power to the Secretary. Under the "nondelegation doctrine," Congress may "seek [ ] assistance from another branch" of the Government, as long as "the extent and character of that assistance [are] fixed according to common sense and the inherent needs of Governmental co-ordination." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928). Accordingly, "[i]f Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power." *Id.* at 409.

We have little doubt that the Vaccine Act sets forth such an intelligible principle to guide the Secretary's actions. Again with reference to the statute, Congress has provided the Secretary with both substantive guideposts and procedural requirements that must be observed. For example, the Initial Table in the Act itself operates as an intelligible principle that governs subsequent, administratively created tables. In the Initial Table, Congress identified the vaccines covered by the table, the illnesses or conditions for which compensation might be had, and the time period required for the first symptom or onset of each illness or condition. *See* 42 U.S.C. § 300aa-14(a) (1994). Although Congress gave the Secretary the power to revise the Initial Table by regulation, revised tables must adhere to this same format. *See id.* § 300aa-14(c)(3) (authorizing the Secretary to add or delete from the list of illnesses and conditions, and to change the time periods).

And although the Secretary could in theory delete all entries in the table or, conversely, sweep in all possible illnesses or conditions, the Act constrains the Secretary's discretion. First, the Vaccine Act requires the Secretary to consult with the Advisory Commission on Childhood Vaccines before proposing rules to revise the injury table. *See id.* § 300aa-14(d). This Commission comprises health professionals, members of the public with family members who have suffered vaccine-related injuries or death, and legal representatives of vaccine victims and vaccine manufacturers, and is charged with the task of gathering information on vaccine-related injuries. *See id.* § 300aa-19. The Act also provides for automatic termination of the compensation program if the total number of awards exceeded a specified number within time frames established by Congress. *See id.* § 300aa-34. More generally, the Vaccine Act establishes a broad program to study and reduce the risk of childhood vaccines. *See, e.g.*, National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-360, §§ 312(a)-(d), 313(a), 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-82 (directing the Secretary to request that the Institute of Medicine of the National Academy of Sciences conduct studies exploring the link between childhood vaccines with certain illnesses). Congress clearly intended the Secretary to be guided by the findings from such studies when she decides to promulgate regulations to revise the injury table. *See id.* § 312(c)-(d), 100 Stat. at 3780; 42 U.S.C. § 300aa-14(d) (1994).

Congress provided ample guidance and limits on the Secretary's authority to promulgate revised vaccine injury tables, and thus Congress's commitment of power to the Secretary under the Vaccine Act does not violate

the nondelegation doctrine. Accordingly, the 1995 Table is a valid regulatory enactment.

IV

A

Having determined that the 1995 Table is valid, we finally turn to the merits of the case. Terran's first argument in favor of reversal, notwithstanding the validity of the regulations at issue, is that the 1995 Table should not apply to her, because her claim arose before the effective date of the regulations. That is, Terran argues that because Julie was assertedly injured by a vaccination on August 10, 1992, her claim arose well before the March 1995 effective date of the Table regulations. Terran suggests that to apply the 1995 Table to her case would work an impermissible retroactive application of law. We disagree.

While we concur with Terran's authoritative citation that "retroactivity is not favored in the law," *see Landgraf v. USI Film Prods.*, 511 U.S. 244, 264 (1994), it does not follow that the 1995 Table does not apply to her case. For it is equally clear that "where congressional intent is clear, it governs." *Id.* (quoting *Kaiser Aluminum & Chem. Corp. v. Bonjorno*, 494 U.S. 827, 837 (1990)). Here, the statute specifically states that newly-promulgated Table regulations "shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation." 42 U.S.C. § 300aa-14(c)(4) (1994). Terran's claim was filed in July 1995, four months after the effective date of the new

regulations. *See* 42 C.F.R. § 100.3(c) (1996). This conclusively resolves the question; the 1995 Table applies to Terran's claims. *See Kaiser Aluminum*, 499 U.S. at 837-38.

B

Terran next argues that the Special Master erred in discounting the causation-in-fact testimony of her expert. The Special Master, applying the factors set forth in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), determined that the expert's theory regarding the causal link between the pertussis toxin and Julie's condition did not meet the standards for scientific reliability enunciated in *Daubert*.

Terran first argues that the application of *Daubert* to this realm of expert knowledge, "general medical issues," was erroneous. She suggests that the *Daubert* framework is narrowly intended to prevent the introduction of "junk science" into trials, rather than as a broader tool for analyzing the admissibility of scientific testimony. We disagree. To the extent we had any doubt at all regarding the permissible use of the *Daubert* framework outside the "scientific" areas specifically discussed in that case, the Supreme Court's recent decision in *Kumho Tire Co. v. Carmichael*, 526 U.S. ___, 119 S. Ct. 1167 (1999), has clarified the issue. *Kumho Tire* specifically notes that the general principles of *Daubert* apply broadly to "scientific, technical, or other specialized knowledge," and that the rules of evidence require that the trial judge determine "whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline.' " *Id.* at 1175 (quoting *Daubert*, 509 U.S. at 592). Thus, the Special

Master did not err in analyzing the proffered testimony according to *Daubert*.

Terran next argues that the Special Master improperly applied the *Daubert* factors to the expert's testimony. In particular, Terran suggests that the Special Master erred by requiring the evidence to meet each of the four *Daubert* factors.[2] However, we do not read the Special Master's decision as requiring that Terran's proffered evidence meet all of the *Daubert* factors. Instead, we view the Special Master's analysis as using *Daubert*'s questions as a tool or framework for conducting the inquiry into the reliability of the evidence. *See Kumho Tire*, 119 S. Ct. at 1175 ("[*Daubert*'s] list of factors was meant to be helpful, not definitive."). The Special Master found that the *Daubert* inquiry raised serious questions about the testimony, and thus concluded that the proffered theory of causation was not sufficiently reliable. *See Terran v. Secretary of Health & Human Servs.*, No. 95-45IV, slip op. at 14 (Fed. Cl. (Special Master) Jan. 23, 1998). Because we view the Special Master's application of the *Daubert* factors to be reasonable, *see Kumho Tire*, 119 S. Ct. at 1176 ("[A] trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony."), and do not discern any

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[2] The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community. *See Daubert*, 509 U.S. at 592-95.

abuse of discretion in the analysis, *see Burns v. Secretary of Dept. of Health & Human Services*, 3 F.3d 415, 417-18 (1993) (reviewing the Special Master's evidentiary determinations for abuse of discretion), we affirm the Special Master's decision to discount the testimony.

C

Terran's final argument is that the Special Master, and thus the Court of Federal Claims, did not address her "straightforward" causation-in-fact argument. That is, Terran suggests that while the Special Master rejected her proffered theory of the mechanism of Julie's injury, that court failed to consider whether an alternative and more straightforward clinical explanation of causation was nonetheless correct. As the Court of Federal Claims noted, however, Terran's "straightforward" argument rests entirely upon factual matters resolved against her, as well as upon those which have been held to be insufficient to establish a *prima facie* case. *See Terran v. Secretary of Dept. of Health & Human Servs.*, No. 95-451V, slip op. at 9 (Fed. Cl. July 10, 1998). For example, Terran points to the temporal association of the seizures with the DPT vaccination, which has been held to be insufficient proof of causation. *See Hasler v. United States*, 718 F.2d 202, 205 (Fed. Cir. 1983). Terran also posits that Julie exhibited a unique seizure disorder, even though this requires agreement with the expert testimony rejected as unreliable by the Special Master. In short, our review of the record has not uncovered any finding of fact or conclusion of law that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B) (1994). We thus are compelled to

affirm the Special Master's rejection of Terran's causation-in-fact claim.

V

In summary, we hold that the Vaccine Act does not violate either the Presentment Clause of the Constitution or the nondelegation doctrine that emanates from separation of powers principles. We affirm the ruling by the United States Court of Federal Claims that the 1995 Table applies to these facts, and that Terran failed to present a *prima facie* case for compensation under the Act.

COSTS

No costs.

AFFIRMED

PLAGER, *Circuit Judge*, dissenting.

Under the United States Constitution, Congress may legislatively declare the rights and liabilities of its citizens in one, and only one, way, and that is by a "Bill which shall have passed the House of Representatives and the Senate, [and] shall, before it becomes a Law, be presented to the President of the United States" for approval or veto. U.S. Const. art. I, § 7, cl. 2 ("the Presentment Clause"); *see also Clinton v. New York*, 524 U.S. 417 (1998). Neither one House of Congress acting alone, *see INS v. Chadha*, 462 U.S. 919 (1983), nor the President or

other Executive Branch official may constitutionally enact, amend, or repeal statutes. *See Clinton*, 524 U.S. at 438 ("There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes.").

In this case, Congress purported to provide for the amendment of existing legislation, which was otherwise valid and enforceable by the courts of the United States, in a manner different from that provided in the Constitution, namely by authorizing an Executive Branch official to do it. That effort must necessarily fail. The majority's valiant effort to uphold the purported amended legislation must also fail, since no amount of verbal adroitness can change the reality of what happened. I respectfully dissent.

1.

The essentials of this case are simple. In 1986 Congress enacted legislation, approved by the President, which entitled persons injured by certain childhood vaccines to a financial recovery paid from the Treasury of the United States. The legislation, *inter alia*, set out in detail the particulars of certain injuries caused by the specified vaccines and the evidence of their happening; if a person established those particulars, he or she was entitled to a recovery. The injuries thus described were known as 'table injuries', since the particulars were set out in the legislation in the form of a Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14(a) (1994). Under the legislation as enacted, the detailed provisions contained in the table

remain in effect indefinitely, that is, no 'sunset' or automatic termination provision was included in the legislation.

In a separate subsection of the legislation, § 300aa-14(c)(1)-(4), Congress purported to enable an Executive Branch officer, the Secretary of Health and Human Services, to amend the statute by changing the particulars contained in the table. The Secretary had authority "to modify" the table, § 300aa-14(c)(1); she could "add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided. . . . " § 300aa-14(c)(3). No restraints were placed upon the Secretary's exercise of the power – the power could be exercised at the discretion of the Secretary, when and as the Secretary chose – other than procedural steps which required, among other things, that the Secretary first confer with her Advisory Commission on Childhood Vaccines, and that the action be in the form of a rulemaking.

Some years later, in 1995, the Secretary chose to exercise that power, and purportedly amended the statute. Plaintiff-Appellant in this case alleges that she would be entitled to an award under the terms of the Congressionally-enacted table, but that under the table as amended by the Secretary she is not so entitled. She challenges the application of the amended statute to her case.

Given the clarity with which the Constitution speaks to this question, and the Supreme Court's unequivocal honoring of the Presentment Clause in *Chadha* and *Clinton*, one might suppose that this would be a not-difficult

case to decide. The majority, however, seeks to find a way around the Constitution, and it is to that effort that I now turn.

2.

As a preliminary matter, I agree with the result reached by the majority in Part IIA of its opinion, i.e., that the Court of Federal Claims has jurisdiction to adjudicate Terran's constitutional challenges to the Vaccine Act, though I cannot join the majority's convoluted analysis in reaching that conclusion. The majority devotes considerable energy to analyzing whether Terran's claim is for money damages. The "money damages" requirement for claims before the Court of Federal Claims arises from that court's jurisdiction under the Tucker Act. *See, e.g., United States v. Mitchell*, 463 U.S. 206, 216-17 (1983); *United States v. Testan*, 424 U.S. 392, 398 (1976). While it is true that the Court of Federal Claims is a court of limited jurisdiction, the Tucker Act is not the only statute expressly granting that court jurisdiction.

As the majority seems to recognize, slip op. at 11, the Vaccine Act itself provides the Court of Federal Claims with jurisdiction to determine whether Terran is entitled to compensation and the amount of such compensation. *See* 42 U.S.C. § 300aa-12(a) (1994); *Beck v. Secretary of the Dep't of Health and Human Servs.*, 924 F.2d 1029, 1036 (Fed. Cir. 1991). This grant of jurisdiction is independent of any jurisdictional grant under the Tucker Act. It is therefore unnecessary to consider, as the Court of Federal Claims did, whether Terran's constitutional challenge to the Vaccine Act is based on a "money-mandating provision" of

the Constitution. The only question we need address is whether in exercising its jurisdiction under the Vaccine Act, the Court of Federal Claims may properly consider the constitutional issues presented.

The Court of Federal Claims has jurisdiction "to determine if a petitioner . . . is entitled to compensation under the [National Vaccine Injury Compensation] Program." 42 U.S.C. § 300aa-12(a). Terran raises her constitutional challenge as part of a claim for compensation over which the Court of Federal Claims clearly has jurisdiction. Resolution of that constitutional challenge directly impacts the determination of whether Terran is entitled to compensation. As the majority correctly concludes, the Vaccine Act gives the Court of Federal Claims the power that is necessary to decide the issue of Terran's compensation, including the power to address the constitutional challenge to the Vaccine Act. *See Beck*, 924 F.2d at 1036; *see also Rodriguez v. Secretary of the Dept. of Health and Human Servs.*, 34 Fed. Cl. 57 (1995) (addressing petitioner's claim that special master's interpretation of § 11(c)(1)(D)(i) of the Vaccine Act violates the Equal Protection clause of the Constitution), *aff'd sub nom. Black v. Secretary of the Dep't. Health and Human Servs.*, 93 F.3d 781 (Fed. Cir. 1996).

Moving on to Part IIB of its opinion, the majority there considers at some length whether 42 U.S.C. § 300aa-32 precludes the Court of Federal Claims from reviewing Terran's constitutional claims; the majority concludes it does not. Again, I agree with the majority's conclusion, but I get there simply because § 300aa-32 is irrelevant to the constitutional challenges at issue here.

By its plain language, § 300aa-32 provides for the review of a *regulation* promulgated under the Vaccine Act. The purpose of the 60-day review period limitation is to preclude a later-filed challenge to the correctness of the administrative action, for example, a challenge that the Secretary did not follow proper rulemaking procedures in creating the revised table, or exceeded the scope of authority the statute granted. That type of challenge was often raised in enforcement actions in other areas, environmental law being an example, until Congress inserted counterparts of § 300aa-32 into the appropriate statutes.

Terran's claim in this case is not a challenge to the manner of promulgation or to the content itself of the regulation that amended the 1995 Table. It is instead a challenge to the underlying enabling statute, 42 U.S.C. § 300aa-14(c), that purports to give the Secretary the power to promulgate the regulation at all. Section 300aa-32 does not govern review of the statute. Thus, I find the majority's discussion of whether § 300aa-32 is intended to be always permissive (which I think is simply wrong), and the circumstances, if any, under which judicial review of a regulation beyond the 60-day period is proper, to be unnecessary to the decision in the case.

3.

The heart of my dissent lies in my disagreement with the majority's conclusion in Part IIIA that 42 U.S.C. § 300aa-14(c) does not violate the Presentment Clause of the Constitution. (The majority opinion initially states the question to be one of "separation of powers principles," slip op. at 2, but, as the Supreme Court observed in

Clinton, 524 U.S. at 448, the question of compliance with Art. I, § 7 is a distinctly different question from the question of whether a statute "impermissibly disrupts the balance of powers among the three branches of government.")

Congress enacted into law the initial version of the Vaccine Injury Table by following proper enactment and presentment procedures in accordance with Article I of the Constitution. As noted, the Supreme Court as recently as last year has made clear that the Presentment Clause requires that any modification to a statute must follow those same procedures. *See Clinton*, 524 U.S. at 448-49. Because 42 U.S.C. § 300aa-14(c) gives the Secretary unilateral power to amend the Vaccine Injury Table without complying with the bicameralism and presentment procedures required for legislative acts, the statute violates the Presentment Clause.

The majority holds that the Vaccine Act does not authorize the Secretary to *amend* the original Vaccine Injury Table, but that it merely authorizes the creation of an entirely new table by regulation, the new table of course superseding the old one. That is little more than a transparent attempt to find a verbal formula for disguising the reality of what transpired. The Vaccine Act explicitly provides that the "Secretary may promulgate regulations to *modify* . . . the Vaccine Injury Table." 42 U.S.C. § 300aa-14(c) (1994) (emphasis added). Despite this admission by Congress that it intended to give the Secretary the power to amend the Vaccine Injury Table, the majority concludes that no amendment occurred because the initial Vaccine Injury Table remains codified in its original form.

Indeed, the crux of the majority's argument derives from the following syllogism: "This new table applies only prospectively. . . . The Initial Table remains codified and unaltered, and continues to apply to all petitions filed before the revision. Therefore, the Initial Table is not amended." Slip op. at 17. The unstated major premise is that an amendment that leaves the earlier provision unrepealed means that the earlier provision is not "amended." It does not require much analysis to recognize the fundamental flaw in that argument.

When Congress changes an existing law, for example by increasing the amount of a penalty for prohibited conduct, or by modifying the criteria for an entitlement, it is almost invariably the case that the provisions of the original statute remain in effect for all cases arising prior to the effective date of the amendment, and that the changed requirements apply only prospectively, to newly-arising matters. As the Supreme Court has admonished, "retroactivity [of legislation] is not favored in the law." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 264 (1994), with the result that Congress rarely makes such changes retroactive. Under the majority's syllogistic reasoning, it would follow that Congress does not "amend" a statute when it makes changes in existing legislation, and leaves the earlier enactment unrepealed; only in the rare case of total repeal with retroactivity is the change an "amendment." That conclusion takes generally understood legal terminology and stands it on its head.

Putting aside such verbal obfuscation, what is clear is that, as a result of the regulation promulgated by the Secretary in 1995, the initial Vaccine Injury Table is no longer legally effective with regard to cases arising after

the effective date of the amendment. The Secretary has deleted a provision which, but for the deletion, would be available for the benefit of persons like Terran. Absent the regulation, the original Vaccine Injury Table would continue to apply to Terran and all others similarly situated; with the regulatorily-amended Table, only the amended table applies to those who file their petitions after the effective date of the regulation.

It matters not whether we say, as the majority says, that the original Vaccine Injury Table was not amended, but that just a new Table was put into law, or whether we acknowledge the obvious reality that the then-existing Table was effectively amended by the regulation. The result is the same – the statutory table as enacted by Congress does not apply to petitions filed after the Secretary's regulation took effect. To paraphrase the words the Supreme Court used in *Clinton*, "[i]n both legal and practical effect, the [Secretary] has amended [an Act] of Congress by repealing a portion of [it]," and "[t]he cancellation of one section of a statute may be the functional equivalent of a partial repeal even if a portion of the section is not canceled." *Clinton*, 524 U.S. at 438, 441.

In further support of its judgment, the majority suggests that the statute by inference has a 'sunset' provision. That simply is not the case. Congress did not decide when the initial Vaccine Injury Table would become ineffective, either by specifying a date or by defining a particular event that would render the initial table ineffective. To suggest, as the majority does, that the Secretary's action is an event selected by Congress to trigger the effective repeal of the initial Vaccine Injury Table is nothing more than circular reasoning, for it is the Secretary's

action in amending the table that itself "repeals" the initial Vaccine Injury Table.

Congress could have chosen to write the statute differently. If Congress in the Vaccine Act had specified certain external events upon the happening of which the enacted table became no longer effective, and at which time the Secretary was to create a revised injury table, and left to the Secretary the determination of when the specified events in fact occurred, the analysis *might* be different. *See Clinton*, 524 U.S. at 445 (explaining that the Tariff Act of 1890 was upheld in *Field v. Clark*, 143 U.S. 649 (1892), because "Congress itself made the decision to suspend or repeal the particular provisions at issue upon the occurrence of particular events subsequent to enactment, and it left only the determination of whether such events occurred up to the President"). But we are not presented with such a situation. The Vaccine Act gives the Secretary complete authority to modify the table, unrestrained by any prerequisite conditions established by Congress, beyond those procedural steps alluded to earlier.

As an alternative, in enacting the Vaccine Act Congress, presumably without violating the Constitution, might have established appropriate criteria under which the Secretary was given authority to create the initial table through an administrative rulemaking procedure, along with the power to revise the table from time to time consistent with those criteria. Congress, however, did not choose this route either, and instead, for whatever reason, included the initial Vaccine Injury Table in the statute itself. Having done so, Congress can render the enacted statute inapplicable to those who come within it only by

repealing or amending the statute in compliance with the bicameralism and presentment procedures of Article I of the Constitution.

The majority's statement, slip op. at 17, that Congress intended that the Secretarially-revised table would supersede its statutory table is irrelevant. *See Clinton*, 524 U.S. at 445-46 ("The fact that Congress intended such a result is of no moment."). Thus there is little question that § 300aa-14(c), as Congress wrote it and which purports to empower the Secretary to modify the statutorily-created Vaccine Injury Table, violates the Presentment Clause of the Constitution.[1]

4.

Words have consequences. The Constitution's constraints have served us well. Judges regularly attend to the constraints the Constitution places upon their own performance, such as the requirement for a genuine "case" or "controversy" before a federal court may exercise judicial power. *See* U.S. Const. art. III, § 2. When a case is before us, it is our obligation under the law to ensure that the other Branches equally conform to the Constitution's mandates, even when doing otherwise would seem to be simpler or more convenient.

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[1] Because I conclude that 42 U.S.C. § 300aa-14(c) clearly violates the Presentment Clause, I find it unnecessary to address the more difficult question of whether the statute as written complies with the minimum requirements for a valid delegation of legislative power, the issue considered by the majority in Part IIIB. Therefore, I do not join that part of the majority's opinion.

Because I would hold that the 1995 attempt by the Secretary to revise the initial Vaccine Injury Table is of no legal effect, I would not reach Plaintiff's alternative theory of causation-in-fact which the majority addresses in Part IV of its opinion. Instead, I would vacate the judgment of the Court of Federal Claims, and remand the case to that court with instructions to analyze Terran's claims under the legislatively-enacted table in 42 U.S.C. § 300aa-14(a), and to process her claims accordingly. I respectfully dissent from the contrary conclusion reached by the majority.

Supreme Court, U.S.
FILED
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Nos. 99-1747 and 99-1749

In the Supreme Court of the United States

FRANK O'CONNELL AND LISA O'CONNELL, LEGAL REPRESENTATIVES OF THEIR DAUGHTER, KELLI-ANN O'CONNELL, PETITIONERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES

MICHELE Y. TERRAN, AS LEGAL REPRESENTATIVE OF JULIE F. TERRAN, A MINOR, PETITIONER

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998), a provision of the National Childhood Vaccine Injury Act of 1986 that allows the Secretary of Health and Human Services to promulgate regulations embodying modifications to an initial Vaccine Injury Table set out in the Act, violates the Presentment Clause of the Constitution Art. I, § 7, Cl. 2, or represents an unconstitutional delegation of legislative power.

2. In No. 99-1749, whether the United States Court of Appeals for the Federal Circuit applies a permissible standard for proof of causation in compensation proceedings under the Act.

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In the Supreme Court of the United States

No. 99-1747

FRANK O'CONNELL AND LISA O'CONNELL, LEGAL REPRESENTATIVES OF THEIR DAUGHTER, KELLI-ANN O'CONNELL, PETITIONERS

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BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals in No. 99-1749 (99-1749 Pet. App. 1a-40a) is reported at 195 F.3d 1302. The opinion of the Court of Federal Claims in that case (99-1749 Pet. App. 41a-58a) is reported at 41 Fed. Cl. 330, and the opinion of the Special Master (99-1749 Pet. App. 59a-92a) is unreported.

The opinion of the court of appeals in No. 99-1747 (99-1747 Pet. App. 1-5) is unreported. The opinion of the Court of Federal Claims (99-1747 Pet. App. 34-41) is reported at 40 Fed. Cl. 891. The opinion of the Special Master (99-1747 Pet. App. 7-33) is unreported.

JURISDICTION

The judgments of the court of appeals were entered on October 27, 1999 (No. 99-1749) and November 1, 1999 (No. 99-1747). Petitions for rehearing were denied on February 2, 2000 (99-1747 Pet. App. 45-46; 99-1749 Pet. App. 93a-94a). The petitions for a writ of certiorari were filed on May 1, 2000 (No. 99-1749) and May 2, 2000 (No. 99-1747). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Congress enacted the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act or the Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (codified at 42 U.S.C. 300aa-1 *et seq.* (1994 & Supp. IV 1998)), to promote national childhood immunization programs by establishing a tax-based federal compensation scheme for children injured by vaccines, thus reducing the number of traditional tort actions filed against vaccine manufacturers. See Pet. App. 5a-6a.[1] The Act first creates a National Vaccine Program, "to achieve optimal prevention of naturally occurring human infectious diseases through immunization and to achieve optimal prevention of the adverse reactions to vaccines." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. I, at 9 (1986); see 42 U.S.C. 300aa-1 to 300aa-6. It then establishes a National Vaccine Injury Compensation Program (the

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[1] Unless otherwise noted, appendix citations are to the appendix to the petition in No. 99-1749.

Program), funded by a special tax on vaccines, under which "compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-15(i); see also 26 U.S.C. 9510 (1994 & Supp. IV 1998).

Claimants under the Program may establish a right to compensation in one of two ways. An injury is presumed to have been caused by a vaccine, and therefore to be compensable, if it is listed on the Program's Vaccine Injury Table (the Table) and first manifests itself within a set period of time, also prescribed by the Table, after administration of the vaccine. See 42 U.S.C., 300aa-14(a) (1994 & Supp. IV 1998); 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(A); 42 C.F.R. 100.3(a). The Table is supplemented by a set of "qualifications and aids to interpretation" providing relevant definitions and explanations. See 42 U.S.C. 300aa-14(b) (1994 & Supp. IV 1998); 42 C.F.R. 100.3(b). The presumption of causation, where it applies, may be rebutted by evidence that the injury was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300aa-13(a)(1)(B). If a claimant's injury is not presumed compensable under the Table, the claimant may nonetheless obtain compensation by demonstrating, by a preponderance of the evidence, that the vaccine in fact caused or significantly aggravated the injury. 42 U.S.C. 300aa-11(c)(1)(C)(ii), 300aa-13(a).

A claimant under the Program is never required to demonstrate that a vaccine was defective or that its manufacturer was negligent. The compensation available includes unreimbursed medical expenses, rehabilitation, special education, vocational training, residential and custodial care, special equipment, lost earnings, pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(a) and (e). A claimant who is dis-

satisfied with an award made under the Program may reject the award and litigate her claim under state tort law, subject to certain limitations. 42 U.S.C. 300aa-11(a), 300aa-21. Applicable statutes of limitations are tolled while the claimant exhausts the alternative remedy provided by the Act. 42 U.S.C. 300aa-16(c).

The Act itself establishes an "initial" Vaccine Injury Table (the Initial Table), and it authorizes the Secretary of Health and Human Services to "promulgate regulations to modify" the Table by adding or deleting injuries or changing the onset periods that trigger a presumption of compensability. See 42 U.S.C. 300aa-14(c)(1) to (3) (1994 & Supp. IV 1998). The legislative history indicates Congress's expectation that the Secretary would make appropriate changes to the Initial Table once "research on vaccine injury and vaccine safety * * * provide[d] more definitive information about the incidence of vaccine injury." H.R. Rep. No. 908, *supra*, at 18. Changes to the Table apply to petitions for compensation that are filed after the effective date of the final regulation adopting the change. 42 U.S.C. 300aa-14(c)(4) (1994 & Supp. IV 1998).

The Act establishes an Advisory Commission on Childhood Vaccines (ACCV) that includes health professionals, legal experts, interested citizens (including parents of children with vaccine-related injuries), and federal officials. See 42 U.S.C. 300aa-5, 300aa-19. The Secretary is required to provide the ACCV with a copy of proposed regulations before issuing them for notice and comment. 42 U.S.C. 300aa-14(d) (1994 & Supp. IV 1998). The ACCV may also ask the Secretary to propose regulations to amend the Table, and it reviews such requests made by others. The Secretary must publicly explain any decision not to undertake a rule-

making proceeding in response to a request. 42 U.S.C. 300aa-14(c)(2) (1994 & Supp. IV 1998).

2. Section 312 of the Act, 100 Stat. 3779-3780, directs the Secretary to "complete a review of all relevant medical and scientific information" on the relationship between certain vaccines and illnesses, to make and publish findings on specified questions, and to "propose regulations to amend the Vaccine Injury Table * * * as a result of such findings." The Secretary arranged for the Institute of Medicine (IOM), an arm of the National Academy of Sciences, to conduct the required study, and the Institute released its report in 1991. See Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* (Christopher P. Howson et al. eds., 1991) (the IOM Report).

The Secretary referred the IOM Report to the National Vaccine Advisory Committee (NVAC), a Public Health Service task force (the Task Force), and the ACCV. Based on the report's conclusion that there was no credible evidence of prolonged neurological damage from diphtheria-pertussis-tetanus (DPT) vaccines, the Task Force and the NVAC recommended that the Table be revised to delete encephalopathy, hypotonic hyporesponsive episode (HHE), and residual seizure disorders (RSD) as conditions presumptively associated with DPT vaccination. The ACCV concurred with respect to HHE and RSD, but it recommended that the Table continue to cover some forms of encephalopathy, under a more precise standard. In 1992 the Secretary issued proposed regulations adopting the ACCV approach. See *O'Connell* v. *Shalala*, 79 F.3d 170, 174-175 (1st Cir. 1996).[2] In 1995,

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[2] In 1993, the Secretary requested that the IOM review a newly published follow-up study of acute childhood neurological

the Secretary issued a final rule removing HHE and RSD from the Table, and modifying the definition of encephalopathy. See 42 C.F.R. 100.3(a) and (b)(2); 60 Fed. Reg. 7678-7696. The revised Table became effective on March 10, 1995, for all petitions filed after that date. See 42 C.F.R. 100.3(c).

Petitioners Francis and Lisa O'Connell sought judicial review of the 1995 regulation under the procedure set out in 42 U.S.C. 300aa-32. The United States Court of Appeals for the First Circuit concluded that "[t]he Secretary had authority to issue the regulations * * *, and she exercised that authority in a procedurally appropriate and substantively permissible manner." *O'Connell*, 79 F.3d at 182. In that proceeding, the O'Connell petitioners did not challenge the constitutionality of the Act.

3. *No. 99-1749 (Terran).* Petitioner Terran sought compensation under the Act on the ground that her daughter Julie first showed signs of RSD and encephalopathy on the day after her third DPT vaccination. Neither RSD nor Julie's non-acute encephalopathy gave rise to a presumption of compensability under the revised Table. Pet. App. 79a. After considering the evidence, the Special Master concluded that petitioner had not shown by a preponderance of the evidence that the DPT vaccine caused Julie's chronic encephalopathy or her afebrile seizures. *Id.* at 87a-91a. He accordingly denied compensation. *Id.* at 91a.

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illnesses. See 60 Fed. Reg. 7685 (1995). The IOM concluded that the evidence suggested a causal relation between DPT vaccines and certain nervous system dysfunctions in children who experienced acute neurologic illness shortly after vaccination. The Secretary reopened the regulatory comment period to allow comment on the new IOM report. See *O'Connell*, 79 F.3d at 175.

a. The Court of Federal Claims sustained the Special Master's decision. Pet. App. 41a-58a. The court concluded that it lacked jurisdiction to consider petitioner's constitutional argument that the Secretary could not modify the Initial Table. *Id.* at 47a-48a. It also held that petitioner's challenge to the revising regulations was untimely or foreclosed by previous litigation, *id.* at 48a-49a, and that application of the revised Table to petitioner's case was not impermissibly retroactive, *id.* at 49a-51a. On the merits, the court applied the standard of review set out in 42 U.S.C. 300aa-12(e)(2), and concluded that the Special Master's determinations with respect to causation were not arbitrary or capricious. Pet. App. 51a-58a.

b. The court of appeals affirmed. Pet. App. 1a-40a. Unlike the Court of Federal Claims, the court of appeals held (*id.* at 10a-16a) that petitioner was not barred from challenging the validity of the Secretary's 1995 regulations modifying the Initial Table, and that the court had jurisdiction over petitioner's claim that Congress could not constitutionally allow the Secretary to make those modifications.

Reviewing the history of the Vaccine Act (Pet. App. 5a-9a), the court explained (*id.* at 7a) that "Congress included the Initial Table in the * * * legislation, rather than delegating the creation of the first injury table to the Secretary, because it was concerned that the administrative process would significantly delay the implementation of the Vaccine Compensation Program." Congress gave the Secretary authority to promulgate regulations modifying the Table, however, because it "intended the Secretary to revise and update the Initial Table with more accurate information that would become available as a result of the research on

vaccine injuries mandated by the Vaccine Act" itself. *Id.* at 8a.

The court rejected petitioner's contention that such an arrangement violates the Presentment Clause of the Constitution (Art. I, § 7, Cl. 2). Pet. App. 17a-23a. Considering the matter in context, the court was "convinced that the Vaccine Act does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations as contemplated in the Act." *Id.* at 18a. The court noted that regulations promulgated by the Secretary "do[] not change in any way the original injury table," but rather promulgate a new Table that applies only prospectively. *Id.* at 19a. Analogizing that process to a routine "sunset" provision, the court reasoned that Congress had merely "itself decided to render the Initial Table ineffective upon the Secretary's action" in promulgating a replacement Table by regulation. *Id.* at 20a.

The court distinguished this case from *Clinton* v. *City of New York*, 524 U.S. 417 (1998), which invalidated the Line Item Veto Act, on three grounds. First, the line-item veto had to be exercised quickly, and was therefore "necessarily based on the same conditions contemplated by Congress" when it passed the affected legislation. Pet. App. 21a. In contrast, replacement of the Initial Table set out in the Vaccine Act itself by a later regulatory Table is "contingent on conditions that did not exist when [the Act] was passed." *Ibid.* Congress simply "anticipated that the facts underlying its legislation might change in the future," and granted the Secretary appropriate authority to establish a superseding Table, through the usual administrative process, "when more accurate information linking vaccines to injuries became available." *Ibid.*

Second, unlike the Line Item Veto Act, which "provided little constraint on the President's discretion to cancel a particular appropriation line item," the Vaccine Act sets forth "detailed procedures and substantive considerations" that "channel" the Secretary's discretion. Pet. App. 21a-22a. And third, whereas *Clinton* concluded that the President was "clearly contravening Congress's policy judgment when he canceled spending items under the Line Item Veto Act," under the Vaccine Act "the Secretary was executing congressional policy when she promulgated the 1995 Table." *Id.* at 22a.

The court of appeals also rejected petitioner's claim that the Vaccine Act effects an unconstitutional delegation of legislative power. Pet. App. 23a-25a. The court noted the existence of various "substantive guideposts and procedural requirements" (*id.* at 23a) under the Act: Revised Tables "must adhere to [the] same format" as the Initial Table; the Secretary must consult with the ACCV before proposing revised regulations; the compensation program automatically terminates if the total number of awards exceeds a specified number within a specified period; and the Act establishes a "broad program to study and reduce the risk of childhood vaccines," which "Congress clearly intended [to guide] the Secretary * * * when she decides to promulgate regulations to revise the injury table." *Id.* at 24a- 25a. Under those circumstances, the court concluded, "Congress provided ample guidance and limits on the Secretary's authority to promulgate revised vaccine injury tables," and therefore stayed within the permissible bounds of delegation. *Id.* at 25a.

Turning to the merits of petitioner's case, the court rejected the argument that the Special Master should have evaluated the claim using the Initial Table be-

cause Julie Terran's condition manifested itself before the effective date of the 1995 regulations. Pet. App. 25a-26a. The court explained that the Act's specific direction that new regulations would govern "petitions for compensation * * * filed after the[ir] effective date" was sufficient to "conclusively resolve[] the question" of applicability against petitioner. *Id.* at 26a.

Finally, the court considered and rejected petitioner's argument that the Special Master erred by "discounting the causation-in-fact testimony of [petitioner's] expert" and resolving the causation question against petitioner. Pet. App. at 26a-29a. The court held that the Master's conclusions with respect to the expert testimony were reasonable (*id.* at 26a-28a), and its "review of the record [did] not uncover[] any finding of fact or conclusion of law that [was] 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* at 29a (quoting 42 U.S.C. 300aa-12(e)(2)(B)). The court accordingly affirmed the Master's rejection of petitioner's claim.

Judge Plager dissented. Pet. App. 30a-40a. In his view, because Congress "included the initial Vaccine Injury Table in the statute itself," its further provisions "purport[ing] to empower the Secretary to modify the statutorily-created" Table were inconsistent with the Presentment Clause. *Id.* at 39a.

4. *No. 99-1747 (O'Connell).* The O'Connell petitioners sought Vaccine Act compensation on the ground that their daughter Kelli-Ann first showed signs of RSD and encephalopathy on the day after her second DPT vaccination. 99-1747 Pet. App. 8-9 & n.2. Her symptoms did not create a presumption of compensability under the revised Table. *Id.* at 8 n.2. After considering the evidence, the Special Master concluded that petitioners had not shown by a preponderance of

the evidence that the DPT vaccine caused Kelli-Ann to suffer from encephalopathy (*id.* at 26-29) or RSD (*id.* at 30-32). She accordingly denied compensation. *Id.* at 33.

The Court of Federal Claims sustained the Special Master's decision. 99-1747 Pet. App. 34-41. As in *Terran*, the court concluded that it lacked jurisdiction to consider petitioners' constitutional argument that the Secretary could not modify the Initial Table. *Id.* at 37-38, 39-41. The court rejected petitioners' argument that the Special Master had applied too high a standard of proof to their off-Table causation claim, and instead sustained the Master's judgment that petitioners had failed to demonstrate the existence of post-vaccine symptoms meeting "any generally accepted definition of acute encephalopathy." *Id.* at 38; see *id.* at 36-39.

The court of appeals affirmed for the reasons given in its opinion in *Terran*. 99-1747 Pet. App. 1-5. Judge Plager dissented, also for the reasons given in his opinion in *Terran*. *Id.* at 4-5. The court did not reach the Secretary's argument that petitioners' constitutional claim was precluded by their failure to raise it in their previous challenge to the validity of the 1995 regulations. *Id.* at 4.

ARGUMENT

1. Petitioners argue that the Vaccine Act violates the Presentment Clause by authorizing the Secretary to promulgate a revised Vaccine Injury Table that supersedes the Initial Table set out in the Act itself. 99-1747 Pet. 9-17; 99-1749 Pet. 16-21. The court of appeals correctly rejected that contention.

The Presentment Clause regulates the enactment of laws, not Executive rulemaking or other steps in the administration of enacted laws. See, *e.g.*, *INS* v. *Chadha*, 462 U.S. 919, 953 n.16 (1983). While Congress

may not confer on the Executive the power to amend or repeal laws, see *Clinton*, 524 U.S. at 438-441, bicameral passage and presentment are not required as a check on Executive rulemaking because such "administrative activity cannot reach beyond the limits of the statute that created it." *Chadha*, 462 U.S. at 953 n.16.

In this case, the Vaccine Act expressly authorizes and contemplates the issuance of revised Vaccine Injury Tables through administrative rulemaking. See 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998). The only distinction between the authority granted to the Secretary to promulgate those Tables and innumerable other statutory conferrals of regulatory authority on the Executive is that in this instance Congress set out an "Initial Table" in the Act itself, so that there would be a basis for providing compensation under the Act during the period after its passage and before the Secretary could complete the study, consultation, and public comment steps necessary to consider and adopt a revised Table. That distinction is not enough to turn an authorized rulemaking into a statutory "amendment" that would require passage by Congress and presentment to the President.

As the court of appeals recognized (Pet. App. 17a-23a), the Secretary's exercise of her statutory authority to promulgate regulations superseding the Initial Table does not amount to an amendment or partial repeal of the Vaccine Act. The 1995 regulations, which the Act makes applicable to petitions filed after their effective date (see 42 U.S.C. 300aa-14(c)(4) (1994 & Supp. IV 1998)), simply implement Congress's direction to issue regulations making appropriate adjustments to the Initial Table in light of research conducted after the enactment of the Act. See Pet. App. 19a. Congress itself provided that once such regulations were issued

they would supersede contrary provisions in the Initial Table, although only for proceedings commenced after the effective date of the new regulations. Compare *Clinton*, 524 U.S. at 446 n.40 (provision of Rules Enabling Act, 28 U.S.C. 2072(b), that "[a]ll laws in conflict with [procedural] rules [adopted by this Court] shall be of no further force or effect after such rules have taken effect" is valid because "Congress itself made the decision to repeal prior rules upon the occurrence of a particular event—here, the promulgation of procedural rules by this Court"). Such a statutory provision is constitutionally permissible, even if it in some respects "alter[s] the substantive rights" (99-1749 Pet. 17) otherwise conferred by a particular statute. See *Touby* v. *United States*, 500 U.S. 160 (1991) (upholding conferral on the Attorney General of authority to add or remove substances from the schedules of controlled substances initially prescribed by statute); *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394 (1928) (upholding provision authorizing President to raise tariffs, above amounts fixed by statute, under certain conditions); *Field* v. *Clark*, 143 U.S. 649, 680, 690-694 (1892) (upholding provision authorizing President to "suspend" the Tariff Act "for such time as he shall deem just," thereby raising tariffs, if foreign governments were imposing "reciprocally unequal and unreasonable" tariffs on specified commodities).

The court of appeals also properly distinguished the table revision provision in the Vaccine Act from the "line-item veto" provision struck down by this Court in *Clinton* v. *City of New York*. See Pet. App. 20a-22a. Unlike the Vaccine Act, the Line Item Veto Act at issue in *Clinton* did purport to give the President the power to "cancel in whole" certain types of provisions

contained in duly enacted legislation. See 524 U.S. at 436; see also *id.* at 446-447. As the court below explained, this Court's invalidation of that authority turned in large part on the Court's conclusions that the Line Item Veto Act provided few constraints on the President's discretion to cancel particular appropriation items for his own policy reasons; required the President to act within five days of the enactment of a law, so that "the President's action was necessarily based on the same conditions contemplated by Congress" in enacting the measure; and authorized exercises of "veto" authority through which the President was "clearly contravening Congress's policy judgment" concerning the canceled items. Pet. App. 21a-22a. In the present case, by contrast, "Congress set forth detailed procedures and substantive considerations in the Vaccine Act that channel [the Secretary's] discretion" to supersede the Initial Table by regulation; regulations are to be issued under Section 300aa-14(c) after study and consultation and "when more accurate information linking vaccines to injuries bec[omes] available"; and the Secretary is implementing—not contravening—congressional policy when she issues superseding regulations in conformance with the plain provisions of the Act. *Id.* at 21a; compare *Clinton*, 524 U.S. at 443-444, 445.

2. The court of appeals also correctly rejected (Pet. App. 23a-25a) petitioners' argument (97-1747 Pet. 18-25; 99-1749 Pet. 21-26) that the Vaccine Act unconstitutionally delegates legislative power to the Secretary. While Congress may not delegate its legislative power to the Executive Branch, this Court's cases reflect "a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job

absent an ability to delegate power under broad general directives." *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989). Congress may authorize the Executive to promulgate legally binding regulations, so long as it "clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Id.* at 373 (quoting *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946)).

As the court of appeals recognized, the Vaccine Act's directions to the Secretary with respect to revising the Vaccine Injury Table satisfy these requirements. As the court explained, "the Initial Table in the Act itself operates as an intelligible principle that governs subsequent, administratively created tables," because "[i]n the Initial Table, Congress identified the vaccines covered by the table, the illnesses or conditions for which compensation might be had, and the time period required for the first symptom or onset of each illness," and "revised tables must adhere to this same format." Pet App. 24a. In addition, the Act requires the Secretary to undertake further scientific study and to consult with experts and interested parties (compare *Mistretta*, 488 U.S. at 376 n.10), and then to consider, through the normal public notice-and-comment process, whether and how to modify the conditions and symptom-appearance times set out in the Initial Table. See 42 U.S.C. 330aa-1 note (Related Studies); 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998).[3] This sensible use of the

[3] In Section 312(a) and (b) of the Act, 100 Stat. 3779-3780, for example, Congress directed the Secretary to "complete a review of all relevant medical and scientific information * * * on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis" and certain specified illnesses and conditions, and to make and publish findings (through a public consultative process) concerning whether, under what

administrative process properly combines an assignment of regulatory authority to an Executive official with more-than-adequate "substantive guideposts and procedural requirements" (Pet. App. 23a) to guide and limit its exercise—limits that are enforceable through appropriate judicial review. 42 U.S.C. 300aa-32. See, *e.g.*, *Skinner* v. *Mid-America Pipeline Co.*, 490 U.S. 212, 218-219 (1989) (citing various examples of valid conferrals of broad regulatory authority on administrative agencies).[4]

Petitioners object (see 99-1749 Pet. 23-26; 99-1747 Pet. 20-21) to Congress's decision to vest the Secretary with the authority to narrow the coverage of the Initial Table, at least in the absence of new scientific evidence definitively establishing the absence of any causal connection between a vaccine and a type of injury or condition. Nothing in the Constitution or in the text or purposes of the Act, however, supports that suggested limitation on the scope of the Secretary's authority to "add to, or delete from, the [Table's] list of injuries, conditions, and deaths for which compensation may be provided or [to] change the time periods for the first

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conditions, and how quickly such vaccines could reasonably be expected to cause or significantly aggravate those illnesses or conditions. Section 312(c) of the Act then directed the Secretary, at the same time she published those findings, to "propose regulations to amend the [Initial Table] * * * as a result of such findings." *Ibid.*

[4] See also *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946) ("Private rights are protected by access to the courts to test the application of the policy in the light of these legislative declarations."); cf. *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 532-533 (1935) (distinguishing cases upholding broad legislative authorizations on the ground that the statutes considered in those cases provided notice and hearing procedures).

symptom or manifestation" of a compensable condition. 42 U.S.C. 300aa-14(c)(3) (1994 & Supp. IV 1998). To the contrary, Congress presumably conferred regulatory authority in those broad terms because it understood that adapting the Initial Table, in light of developing scientific knowledge, would require the exercise of informed administrative judgment that might either increase or decrease the scope of presumptive, Table-based compensability (always, of course, leaving claimants the opportunity to receive compensation by showing that a causal relationship is more likely than not on the facts of a particular case). Cf. *Touby*, 500 U.S. at 162 (upholding provisions authorizing the Attorney General to remove or add substances to initial statutory schedules of controlled substances); *Yakus* v. *United States*, 321 U.S. 414, 425 (1944) (authorized activities may "call for the exercise of judgment, and for the formulation of subsidiary administrative policy within the prescribed statutory framework").

3. Petitioner Terran contends (99-1749 Pet. 26-30) that this Court should grant review to resolve differences in the way different panels of the Federal Circuit have approached the question of "causation-in-fact" in Vaccine Act cases. Even if there were such an intra-circuit conflict, it would be a matter for the court of appeals itself to resolve. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957). But the cases petitioner cites do not announce materially different standards of proof. Compare *Knudsen* v. *Secretary of the Dep't of HHS*, 35 F.3d 543, 548-549 (Fed. Cir. 1994) (citing *Bunting* v. *Secretary of the Dep't of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991), and *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)) ("The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause

and effect is 'logical' and legally probable, not medically or scientifically certain," but that conclusion must be supported by a sound and reliable medical or scientific explanation.), with *Grant* v. *Secretary of the Dep't of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (requiring "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury").

The cases petitioner Terran cites do differ in that the first two, *Grant* and *Strother* v. *Secretary of the Dep't of HHS*, 21 Cl. Ct. 365 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991), involved causation in "off-Table" cases, where the petitioner is not entitled to a presumption of compensability, while the latter two, *Knudsen* and *Bunting*, were Table cases, where the petitioner is entitled to compensation unless the Secretary can show that the claimant's condition is more likely than not traceable to an identifiable cause other than the vaccine.[5] Thus, while all four cases require the same proof of causation, they properly allocate the burden of persuasion to different parties, based on whether the claimant is entitled to a Table-based presumption of compensability. In the present cases, petitioners had the burden of showing causation-in-fact to support their non-Table claims. The Special Master and the courts

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[5] In demonstrating that "factors unrelated to the administration of the vaccine" caused a child's injury, 42 U.S.C. 300aa-13(a)(1)(B), the Secretary must meet the same standard of proof that applies to a petitioner's proof of causation in "off-Table" cases. See *Knudsen*, 35 F.3d at 548. It is not enough for the Secretary to identify some other possible cause of an injury; rather, she must show, by a preponderance of the evidence, that an identifiable alternate cause "in the particular case [was] shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." *Ibid.* (quoting 42 U.S.C. 300aa-13(a)(2)).

below concluded, after reviewing the relevant evidence, that petitioners had not borne that burden. That fact-bound determination does not warrant review by this Court.

4. We note, finally, three additional factors that weigh against review in these cases.[6] First, as the Secretary argued in the court of appeals, the O'Connell petitioners' constitutional claims are barred because they could have been, but were not, raised in petitioners' previous lawsuit, brought under the statutory provision for judicial review set out in 42 U.S.C. 300aa-32, challenging the validity of the Secretary's 1995 regulations. See p. 6, *supra*; 99-1747 Pet. App. 4 (declining to reach preclusion question in light of resolution of merits issue in *Terran*); Gov't C.A. Br. 22-29 (No. 98-5134); see generally, *e.g.*, *Federated Dep't Stores, Inc.* v. *Moitie*, 452 U.S. 394, 398-399 (1981).

Second, as the Secretary also argued below, petitioner Terran did not challenge the validity of the Secretary's 1995 regulation in the manner and within the time specified by Congress in 42 U.S.C. 300aa-32. See Pet. App. 13a-16a (rejecting this argument), 48a-49a (accepting the argument, at least for non-constitutional claims); Gov't C.A. Br. 18-20 (No. 98-5161). Although the court of appeals disagreed with the Secretary's argument that the failure to bring such a challenge precluded petitioner Terran's present suit, that question would remain open should the Court

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[6] In light of these factors, and because petitioners do not rely upon (or even cite) the District of Columbia Circuit's decision in *American Trucking Associations* v. *United States Environmental Protection Agency*, 175 F.3d 1027 (1999), there is also no reason to hold the petitions in these cases pending this Court review of that decision in No. 99-1257, *Browner* v. *American Trucking Associations*, cert. granted (May 22, 2000).

grant review. See, *e.g.*, *Northwest Airlines, Inc.* v. *County of Kent*, 510 U.S. 355, 364 (1994); *Thigpen* v. *Roberts*, 468 U.S. 27, 29-30 (1984).

Third, Section 322 of the original Vaccine Act, 100 Stat. 3783, sets out a somewhat unusual "nonseverability" clause: "If any provision of this title [including provisions codified at 42 U.S.C. 300aa-1 through 300aa-34] or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid."[7] The existence of that provision underscores that petitioners' constitutional challenge to the Act's grant of regulatory authority to the Secretary also raises potentially difficult questions of remedy, severability, and redressability. Compare *Chadha*, 462 U.S. at 931-935 (addressing severability and related standing argument); *McCorkle* v. *United States*, 559 F.2d 1258, 1261 (4th Cir. 1977) (concluding that legislative veto provision was not severable and dismissing action), cert. denied, 434 U.S. 1011 (1978); cf. *Friends of the Earth, Inc.* v. *Laidlaw Envtl. Servs., Inc.*, 120 S. Ct. 693, 703-704, 706-708 (2000) (treating redressability as an aspect of Article III standing); Israel Friedman, *Inseverability Clauses in Statutes*, 64 U. Chi. L. Rev. 903 (1997). The possible need to address those issues before reaching the questions petitioners seek to present counsels against granting review in these cases.

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[7] Section 322 has been amended in ways not material to the point made here. See 42 U.S.C. 300aa-1 note (severability).

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully submitted.

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AUGUST 2000